EXHIBIT A-30

IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
TRIAL DIVISION – CIVIL

TERRAINE ABDULLAH, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	MARCH TERM, 2022 No. 220302583
HOLLI CARTER, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	MARCH TERM, 2022 No. 220302588
SHONDERA DRAYTON, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	MARCH TERM, 2022 No. 220302594
BRANDY GOODMOND, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	APRIL TERM, 2022 No. 220400208
BRANDY GOODMOND, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	APRIL TERM, 2022 No. 220400212
TONYA GRAY, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	APRIL TERM, 2022 No. 220400216
JANEE HENDERSON, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	APRIL TERM, 2022 No. 220400127

DELQUAN HINES, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	APRIL TERM, 2022 No. 220400136
SHEMIKA JOHNSON, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	APRIL TERM, 2022 No. 220400162
KRISTEN KAJUFFA, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	MARCH TERM, 2022 No. 220302978
NAFEESAH MAYS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	MARCH TERM, 2022 No. 220302963
CATHERINE McMILLIAN, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	APRIL TERM, 2022 No. 220400140
DAMEKA MOMENT, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	APRIL TERM, 2022 No. 220400142
ERICA PADILLA, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	MARCH TERM, 2022 No. 220302969
NYDIA PARKER, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	MARCH TERM, 2022 No. 220302983

ALEXANDRIA ROSS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	MARCH TERM, 2022 No. 220302981
LOREN SANDERS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	APRIL TERM, 2022 No. 220400153
SAMAYA SHORT, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	APRIL TERM, 2022 No. 220400159
ALICE STILLS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	MARCH TERM, 2022 No. 220302617
CHRISTINA TAYLOR, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	MARCH TERM, 2022 No. 220302606
NATISHA THOMAS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	MARCH TERM, 2022 No. 220400158
TRINA WALKER-SAVAGE and CLIFTON ISAIAH SAVAGE, JR., et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : : :	MARCH TERM, 2022 No. 220400156
JEANNATE WATSON, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	MARCH TERM, 2022 No. 220302967

ROBERT WHITFIELD, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	APRIL TERM, 2022 No. 220400145
GINA WIEGER, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	MARCH TERM, 2022 No. 220302614
GINA WIEGER, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	MARCH TERM, 2022 No. 220302601
SHANITA WIGGINS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	MARCH TERM, 2022 No. 220302986
MELVENIA WILLIAMS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	APRIL TERM, 2022 No. 220400141
IVYANN WITHERSPOON, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	APRIL TERM, 2022 No. 220400138

ORDER OF THE COURT

On this ____ day of _____, 2023, upon consideration of defendant Abbott Laboratories' preliminary objections to plaintiffs' complaints, its brief in support, and any response thereto, it is hereby ORDERED that defendant Abbott Laboratories' preliminary objections to plaintiffs' complaints are SUSTAINED. It is further ORDERED that Counts I through V of plaintiffs' complaints are DISMISSED as to Abbott Laboratories.

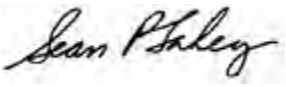
BY THE COURT:

_____

NOTICE TO PLEAD

To: Plaintiffs

You are hereby notified to file a written response to the enclosed Preliminary Objections within twenty (20) days from service hereof or a judgment may be entered against you.



Counsel for Defendant Abbott Laboratories

TROUTMAN PEPPER HAMILTON SANDERS LLP
Sean P. Fahey (PA Bar No. 73305)
3000 Two Logan Square
Philadelphia, PA 19103
215.981.4296
Sean.Fahey@troutman.com

Ronni E. Fuchs (PA Bar No. 65561)
301 Carnegie Center, Suite 400
Princeton, NJ 08540
609.951.4183
Ronni.Fuchs@troutman.com

CAMPBELL CONROY & O'NEIL, P.C.
Joseph E. O'Neil (PA Bar No. 29053)
Meaghann C. Porth (PA Bar No. 307629)
Ryan J. O'Neil (PA Bar No. 314034)
1205 Westlakes Drive, Suite 330
Berwyn, PA 19312
610.964.1900
JONeil@CampbellTrialLawyers.com
MPorth@campbell-trial-lawyers.com
RONeil@campbell-trial-lawyers.com

JONES DAY
Marques Hillman Richeson (admitted *pro hac vice*)
901 Lakeside Avenue
Cleveland, OH 44114
216.586.7195
mhricheson@jonesday.com

Jennifer B. Flannery (PA Bar No. 74546)
1221 Peachtree Street, N.E., Suite 400
Atlanta, GA 30361
404.581.8008
jbflannery@jonesday.com

Attorneys for Defendant Abbott Laboratories

IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
TRIAL DIVISION – CIVIL

TERRAINE ABDULLAH, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	MARCH TERM, 2022 No. 220302583
HOLLI CARTER, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	MARCH TERM, 2022 No. 220302588
SHONDERA DRAYTON, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	MARCH TERM, 2022 No. 220302594
BRANDY GOODMOND, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	APRIL TERM, 2022 No. 220400208
BRANDY GOODMOND, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	APRIL TERM, 2022 No. 220400212
TONYA GRAY, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	APRIL TERM, 2022 No. 220400216
JANEE HENDERSON, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	APRIL TERM, 2022 No. 220400127

DELQUAN HINES, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	APRIL TERM, 2022 No. 220400136
SHEMIKA JOHNSON, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	APRIL TERM, 2022 No. 220400162
KRISTEN KAJUFFA, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	MARCH TERM, 2022 No. 220302978
NAFEESAH MAYS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	MARCH TERM, 2022 No. 220302963
CATHERINE McMILLIAN, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	APRIL TERM, 2022 No. 220400140
DAMEKA MOMENT, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	APRIL TERM, 2022 No. 220400142
ERICA PADILLA, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	MARCH TERM, 2022 No. 220302969
NYDIA PARKER, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	MARCH TERM, 2022 No. 220302983

ALEXANDRIA ROSS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	MARCH TERM, 2022 No. 220302981
LOREN SANDERS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	APRIL TERM, 2022 No. 220400153
SAMAYA SHORT, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	APRIL TERM, 2022 No. 220400159
ALICE STILLS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	MARCH TERM, 2022 No. 220302617
CHRISTINA TAYLOR, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	MARCH TERM, 2022 No. 220302606
NATISHA THOMAS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	MARCH TERM, 2022 No. 220400158
TRINA WALKER-SAVAGE and CLIFTON ISAIAH SAVAGE, JR., et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : : :	MARCH TERM, 2022 No. 220400156
JEANNATE WATSON, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	MARCH TERM, 2022 No. 220302967

ROBERT WHITFIELD, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	APRIL TERM, 2022 No. 220400145
GINA WIEGER, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	MARCH TERM, 2022 No. 220302614
GINA WIEGER, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	MARCH TERM, 2022 No. 220302601
SHANITA WIGGINS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	MARCH TERM, 2022 No. 220302986
MELVENIA WILLIAMS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	APRIL TERM, 2022 No. 220400141
IVYANN WITHERSPOON, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	APRIL TERM, 2022 No. 220400138

DEFENDANT ABBOTT LABORATORIES'
PRELIMINARY OBJECTIONS TO PLAINTIFFS' COMPLAINTS

In the above-captioned twenty-nine nearly identical lawsuits, plaintiffs attack—without basis—specialized infant formulas and fortifiers essential to the survival and development of premature infants in Neonatal Intensive Care Units ("NICUs"). Plaintiffs allege that medical professionals at their birth hospitals administered Abbott's and/or Mead Johnson's cow milk-based infant nutrition products to them as newborns, and that they were injured as a result. Compl. ¶¶ 1–2.[1] Each complaint is filed by a parent ("plaintiff-parent") on his or her own behalf, and also as a parent and natural guardian of the child plaintiff ("plaintiff") (together, "plaintiffs").

Pursuant to Rules 1028(a)(2), 1028(a)(3), and 1028(a)(4) of the Pennsylvania Rules of Civil Procedure, defendant Abbott Laboratories ("Abbott") preliminarily objects to each of the complaints on the basis that plaintiffs' claims are legally insufficient, are pled with insufficient specificity, and fail to conform to a rule of court. In support of its preliminary objections, Abbott states the following:

1. Plaintiffs filed each of these actions against defendants Mead Johnson & Company LLC, Mead Johnson Nutrition Company (together, "Mead Johnson"), Abbott, and a hospital defendant (collectively, "defendants"), alleging that medical professionals at the hospital defendant administered Abbott's and/or Mead Johnson's cow's milk-based infant nutrition products to plaintiff, and that plaintiff was injured as a result. Compl. ¶¶ 1–2.

[1] The substantive allegations against Abbott in all twenty-nine complaints are nearly identical. The complaint in the following eighteen cases uses identical paragraph numbering: *Abdullah; Carter; Drayton; Henderson; Hines; Johnson; McMillian; Moment; Sanders; Short; Taylor; Thomas; Walker-Savage; Whitfield; Wieger (M.P.); Wieger (S.P.); Williams; and Witherspoon*. Paragraph numbers cited in the text of these preliminary objections are to this complaint ("reference complaint") (attached as Exhibit A). Paragraph numbers for the other eleven complaints are cited in footnotes herein. For *Goodmond (Rya. G.); Goodmond (Ryh. G.); Gray; Kajuffa; Mays; Padilla; Parker; Ross; Stills; Watson; Wiggins*, the operative complaint is attached as Exhibit D.

2. In each complaint, plaintiffs bring seven causes of action, five of which are asserted against Abbott and Mead Johnson: strict products liability design defect (Count I), strict products liability failure to warn (Count II), negligence (Count III), intentional misrepresentation (Count IV), and negligent misrepresentation (Count V). The remaining claims (Counts VI and VII) are asserted against the hospital defendant.

I. PRELIMINARY OBJECTION FOR LEGAL INSUFFICIENCY OF ALL CLAIMS.

3. Abbott incorporates the foregoing paragraphs as if set forth herein.

4. Pursuant to Pa. R. Civ. P. 1028(a)(4), a preliminary objection may be filed by any party to a pleading regarding the legal insufficiency of a pleading.

5. "The threshold inquiry in all products liability cases is whether there is a defect which rendered the product unreasonably dangerous." *Weiner v. Am. Honda Motor Co., Inc.*, 718 A.2d 305, 307 (Pa. Super. Ct. 1998). Plaintiffs must aver sufficient facts demonstrating that Abbott's products were unreasonably dangerous for their intended use, precipitating Abbott's duty to warn.

6. Plaintiffs fail to do so. The studies from which plaintiffs quote are inapposite. None of the quoted studies support plaintiffs' bald contention that cow's milk-based feeding products ***cause*** NEC, such that they could be unreasonably dangerous when administered to premature and low birth weight infants.

7. Accordingly, this preliminary objection should be sustained, and all Counts against Abbott should be dismissed.

II. PRELIMINARY OBJECTION FOR LEGAL INSUFFICIENCY OF PLAINTIFFS' STRICT LIABILITY CLAIMS.

8. Abbott incorporates the foregoing paragraphs as if set forth herein.

9. Pursuant to Pa. R. Civ. P. 1028(a)(4), a preliminary objection may be filed by any party to a pleading regarding the legal insufficiency of a pleading.

10. Counts I and II are strict liability claims that require plaintiffs to identify the specific product that allegedly caused plaintiff's injury. *Cummins v. Firestone Tire & Rubber Co.*, 495 A.2d 963, 968 (Pa. Super. Ct. 1985) (Pennsylvania "imposes liability for physical harm caused to the user only upon that person who sold a product in a defective condition. A plaintiff must therefore at least *designate* the product alleged to be defective in order to recover from the one who sells it.") (emphasis added).

11. Plaintiffs fail to do so. Instead, without referring to medical records containing product identification information, they allege, in each case, only that "Abbott's and/or Mead [Johnson]'s products" were administered to plaintiff and caused plaintiff's injuries. Compl. ¶ 74.[2]

12. Accordingly, this preliminary objection should be sustained, and Counts I and II against Abbott should be dismissed.

III. PRELIMINARY OBJECTION FOR LEGAL INSUFFICIENCY OF PLAINTIFFS' NEGLIGENCE CLAIMS.

13. Abbott incorporates the foregoing paragraphs as if set forth herein.

14. Pursuant to Pa. R. Civ. P. 1028(a)(4), a preliminary objection may be filed by any party to a pleading regarding the legal insufficiency of a pleading.

15. Count III is a claim for negligence, requiring plaintiffs to identify the product that injured them and to allege a reasonably close causal connection between Abbott's conduct with respect to that product and the resulting injuries to plaintiffs. *See Cummins*, 495 A.2d at 968. Because plaintiffs fail to identify the specific product giving rise to their claims, they also fail to establish a causal connection between Abbott's conduct and their injuries.

[2] Same allegation found at Compl. ¶ 73: *Kajuffa; Mays; Padilla; Parker; Ross; Stills; Watson; Wiggins.* Compl. ¶ 72: *Goodmond (Ryh G.)*; *Gray.* Compl. ¶ 71: *Goodmond (Rya G.).*

16. Accordingly, this preliminary objection should be sustained, and Count III against Abbott should be dismissed.

IV. PRELIMINARY OBJECTION FOR INSUFFICIENT SPECIFICITY IN PLEADING PLAINTIFFS' MISREPRESENTATION CLAIMS.

17. Abbott incorporates the foregoing paragraphs as if set forth herein.

18. Pursuant to Pa. R. Civ. P. 1028(a)(3), a preliminary objection may be filed by any party to a pleading regarding insufficient specificity in a pleading.

19. Counts IV and V are claims for intentional and negligent misrepresentation; these fraud-based claims are subject to heightened pleading requirements under Pa. R. Civ. P. 1019(b). But plaintiffs fail to allege with particularity that they saw or were otherwise exposed to any purported misrepresentations made by Abbott. They also do not specifically allege who made the supposed misrepresentations, or when they supposedly did so. Moreover, plaintiffs cannot plausibly allege reliance on misrepresentations to which they were not exposed.

20. Accordingly, this preliminary objection should be sustained, and Counts IV and V against Abbott should be dismissed.

V. PRELIMINARY OBJECTION FOR INSUFFICIENT SPECIFICITY IN DIFFERENTIATING BETWEEN DEFENDANTS THROUGHOUT COMPLAINTS.

21. Abbott incorporates the foregoing paragraphs as if set forth herein.

22. Pursuant to Pa. R. Civ. P. 1028(a)(3), a preliminary objection may be filed by any party to a pleading regarding insufficient specificity in a pleading.

23. In the unnumbered paragraph of the complaints appearing before paragraph 1, plaintiffs collectively refer to Abbott and Mead Johnson as "the Defendant Manufacturers" without explaining what relationship, if any, exists between these corporations, or why the acts of Mead Johnson should be attributed to Abbott, or vice versa. Compl. ¶ 1.

24. Paragraphs 1 and 12 of the reference complaint[3] generally allege that plaintiff was given "the Defendant Manufacturers' cow's milk-based" products, without specifying which product from which manufacturer was administered to plaintiff.

25. Paragraph 13 of the reference complaint[4] generally alleges that plaintiff developed necrotizing enterocolitis ("NEC") shortly after being administered the defendant manufacturers' products, again without specifying which product from which manufacturer was administered.

26. Paragraph 43 of the reference complaint [5] alleges that the "Defendant Manufacturers have designed powerful misleading marketing campaigns to deceive parents," without specifying any particular act of deception by any individual defendant, and without providing any details about when, if at all, plaintiffs saw the allegedly misleading marketing campaigns.

27. Across Counts I through V of the complaint, plaintiffs allege wrongful conduct by Abbott and/or Mead Johnson without differentiating between the defendants or specifying each defendant's distinct role in each claim.

28. Because plaintiffs have lumped Abbott and Mead Johnson together without differentiating between the distinct acts or omissions of these distinct corporations, Abbott lacks clarity regarding its alleged role in these cases. Plaintiffs' allegations are thus insufficiently pled under Rule 1028(a)(3).

---

[3] Same allegation found at Compl. ¶ 11: *Kajuffa; Parker; Ross; Wiggins.* Compl. ¶ 12: *Goodmond (Ryh G.)*; *Goodmond (Rya G.); Gray; Mays; Padilla; Stills; Watson.*

[4] Same allegation found at Compl. ¶ 12: *Kajuffa; Parker; Ross; Wiggins.* Compl. ¶ 13: *Goodmond (Ryh G.)*; *Goodmond (Rya G.); Gray; Mays; Padilla; Stills; Watson.*

[5] Same allegation found at Compl. ¶ 42: *Goodmond (Rya G.); Kajuffa; Parker; Ross; Stills; Wiggins.* Compl. ¶ 43: *Goodmond (Ryh G.); Gray; Mays; Padilla; Watson.*

29. Accordingly, all claims against Abbott should be dismissed, or in the alternative, all paragraphs in which plaintiffs fail to differentiate between defendants should be stricken,[6] and this preliminary objection should be sustained.

VI. PRELIMINARY OBJECTION REGARDING PLAINTIFF-PARENTS' TIME-BARRED CLAIMS IN 23 CASES.

30. Abbott incorporates the foregoing paragraphs as if set forth herein.

31. Pursuant to Pa. R. Civ. P. 1028(a)(4), a preliminary objection may be filed by any party to a pleading regarding the legal insufficiency of a pleading.

32. Pennsylvania law establishes a two-year statute of limitations for negligent, intentional, or otherwise tortious conduct. *See* 42 Pa. Cons. Stat. § 5524(2) & (7).

33. While the statute of limitations began running on plaintiff-parent's claims on or around the date of the infant-plaintiffs' birth (second column in the chart below), parent-plaintiffs' complaints in 23 cases were not filed until the date appearing in the third column below – in all instances years after the statute of limitations period expired (fourth column in chart below).

Plaintiff Name	Alleged Date of Birth	Filing Date of Complaint	Time Elapsed from Birth to Filing
Abdullah, Terraine (obo H.S.)	09/12/2006	03/24/2022	15 years and 6 months
Carter, Holli (obo J.C.)	10/06/2014	03/24/2022	7 years and 5 months
Goodmond, Brandy (obo Rya G.)	12/31/2007	04/04/2022	14 years and 3 months
Goodmond, Brandy (obo Ryh G.)	08/01/2010	04/04/2022	11 years and 8 months
Gray, Tonya (obo J.M.)	03/14/2005	04/04/2022	17 years
Henderson, Janee (obo S.C.)	07/15/2007	04/04/2022	14 years and 8 months
Johnson, Shemika (obo W.J.)	06/05/2004	04/04/2022	17 years and 9 months

[6] For example, in the reference complaint, plaintiffs fail to differentiate between defendants in each of the following paragraphs: 1–2, 12–13, 26, 28–31, 33, 35, 41–43, 63, and 65–112.

Plaintiff Name	Alleged Date of Birth	Filing Date of Complaint	Time Elapsed from Birth to Filing
Kajuffa, Kristen (obo B.K.)	01/18/2007	03/29/2022	15 years and 2 months
Mays, Nafeesah (obo A. R.)	07/15/2005	03/29/2022	16 years and 8 months
McMillian, Catherine (obo T.M.)	11/14/2005	04/04/2022	16 years and 4 months
Moment, Dameka (obo A.M.)	11/30/2017	04/04/2022	4 years and 4 months
Padilla, Erica (obo J.C.)	07/30/2007	03/29/2022	14 years and 7 months
Parker, Nydia (obo M.H.)	07/31/2016	03/29/2022	5 years and 7 months
Sanders, Loren (obo Q.S.)	03/17/2007	04/04/2022	15 years
Short, Samaya (obo S.M.)	10/26/2017	04/04/2022	4 years and 5 months
Stills, Alice (obo M.E.)	09/28/2007	03/24/2022	14 years and 5 months
Taylor, Christina (obo I.H.)	10/09/2010	03/24/2022	11 years and 5 months
Thomas, Natisha (obo R.T.)	12/24/2015	04/04/2022	6 years and 3 months
Walker-Savage, Trina, and Clifton Isaiah Savage, Jr.	08/09/2002	040/4/2022	19 years and 7 months
Watson, Jeannate (obo B.I.)	02/05/2015	03/29/2022	7 years and 1 months
Wieger, Gina (obo M.P.)	12/13/2013	03/24/2022	8 years and 3 months
Wieger, Gina (obo S.P.)	12/13/2013	03/24/2022	8 years and 3 months
Wiggins, Shanita (obo T.B.)	01/28/2010	03/29/2022	12 years and 2 months

34. Plaintiff-parents' claims in these cases are thus time-barred.

35. Accordingly, plaintiff-parents' claims in these cases should be dismissed, and this preliminary objection should be sustained.

VII. PRELIMINARY OBJECTION REGARDING PLAINTIFFS' REQUEST FOR PUNITIVE DAMAGES.

36. Abbott incorporates the foregoing paragraphs as if set forth herein.

37. Pursuant to Pa. R. Civ. P. 1028(a)(4), a preliminary objection may be filed by any party to a pleading regarding the legal insufficiency of a pleading.

38. Pursuant to Pa. R. Civ. P. 1028(a)(3), a preliminary objection may be filed by any party to a pleading regarding insufficient specificity in a pleading.

39. Plaintiffs demand punitive damages against Abbott in the *ad damnum* clause of each of Counts I through V.

40. Plaintiffs' demands for punitive damages in Counts III and V are legally insufficient, as the counts plainly sound in negligence and, under Pennsylvania law, punitive damages are not available for claims of "ordinary negligence." *See Martin v. Johns-Manville Corp.*, 494 A.2d 1088, 1097 (Pa. 1985) (citing RESTATEMENT OF TORTS (SECOND) § 908, comment e).

41. Additionally, plaintiffs' demands for punitive damages in each of Counts I through V are insufficiently specific. In particular, plaintiffs merely allege Abbott's conduct was "malicious" without providing any factual support for the same. *See Whiting v. Nationwide Ins. Co.*, 9 Pa. D. & C.3d 789, 792 (1979) (dismissing plaintiffs' punitive damages request where "factual averments in support of . . . conclusory allegations are totally lacking").

42. Accordingly, Abbott respectfully requests that plaintiffs' demands for punitive damages in each of Counts I through V be stricken.

VIII. PRELIMINARY OBJECTION REGARDING PLAINTIFFS' FAILURE TO PROPERLY VERIFY THEIR COMPLAINT.

43. Abbott incorporates the foregoing paragraphs as if set forth herein.

44. Pursuant to Pa. R. Civ. P. 1028(a)(2), a preliminary objection may be filed by any party to a pleading regarding a party's failure to conform to a rule of court.

45. Pa. R. Civ. P. 1024(a) provides that "[e]very pleading containing an averment of fact not appearing of record in the action . . . shall state that the averment . . . is true upon the

signer's personal knowledge or information and belief and shall be verified." *See* Pa. R. Civ. P. 1024(a).

46. Rule 1024(c) provides that the verification "shall be made by one or more of the parties filing the pleading," unless a qualifying exception applies. *See id.* R. 1024(c). In the event the verification is signed by someone other than the filing party, the verification must set forth "the reason why the verification is not made by a party." *See id.*

47. Plaintiffs' complaints are not verified by plaintiffs themselves; instead, they are verified by their counsel. Regardless of whether it was appropriate for plaintiffs' counsel to verify the complaints in this instance, plaintiffs failed to state in the verification why they themselves did not sign them.

48. Plaintiffs failed to conform to Rule 1024(c) in verifying their complaints and, accordingly, Abbott respectfully requests that this Court strike the complaints.

WHEREFORE, pursuant to Pa. R. Civ. P. 1028(a)(2), 1028(a)(3), and (a)(4), Abbott respectfully requests that this Court sustain these preliminary objections and dismiss Counts I, II, III, IV, and V against Abbott.

Dated: June 12, 2023

Respectfully Submitted:

/s/ Sean P. Fahey
Sean P. Fahey (PA Bar No. 73305)
TROUTMAN PEPPER HAMILTON SANDERS LLP
3000 Two Logan Square
Philadelphia, PA 19103
215.981.4296
Sean.Fahey@troutman.com

/s/ Joseph E. O'Neil
Joseph E. O'Neil (PA Bar No. 29053)
Meaghann C. Porth (PA Bar No. 307629)
Ryan J. O'Neil (PA Bar No. 314034)
CAMPBELL CONROY & O'NEIL, P.C.
1205 Westlakes Drive, Suite 330
Berwyn, PA 19312
610.964.6388
JONeil@CampbellTrialLawyers.com
MPorth@campbell-trial-lawyers.com
RONeil@campbell-trial-lawyers.com

/s/ Ronni E. Fuchs
Ronni E. Fuchs (PA Bar No. 65561)
TROUTMAN PEPPER HAMILTON SANDERS LLP
301 Carnegie Center, Suite 400
Princeton, NJ 08540
609.951.4183
Ronni.Fuchs@troutman.com

/s/ Marques Hillman Richeson
Marques Hillman Richeson (admitted *pro hac vice*)
JONES DAY
901 Lakeside Avenue
Cleveland, OH 44114
216.586.7195
mhricheson@jonesday.com

/s/ Jennifer B. Flannery
Jennifer B. Flannery (PA Bar No. 74546)
JONES DAY
1221 Peachtree Street, N.E., Suite 400
Atlanta, GA 30361
404.581.8008
jbflannery@jonesday.com

Attorneys for Defendant Abbott Laboratories

TROUTMAN PEPPER HAMILTON SANDERS LLP
Sean P. Fahey (PA Bar No. 73305)
3000 Two Logan Square
Philadelphia, PA 19103
215.981.4296
Sean.Fahey@troutman.com

Ronni E. Fuchs (PA Bar No. 65561)
301 Carnegie Center, Suite 400
Princeton, NJ 08540
609.951.4183
Ronni.Fuchs@troutman.com

CAMPBELL CONROY & O'NEIL, P.C.
Joseph E. O'Neil (PA Bar No. 29053)
Meaghann C. Porth (PA Bar No. 307629)
Ryan J. O'Neil (PA Bar No. 314034)
1205 Westlakes Drive, Suite 330
Berwyn, PA 19312
610.964.1900
JONeil@CampbellTrialLawyers.com
MPorth@campbell-trial-lawyers.com
RONeil@campbell-trial-lawyers.com

JONES DAY
Marques Hillman Richeson (admitted *pro hac vice*)
901 Lakeside Avenue
Cleveland, OH 44114
216.586.7195
mhricheson@jonesday.com

Jennifer B. Flannery (PA Bar No. 74546)
1221 Peachtree Street, N.E., Suite 400
Atlanta, GA 30361
404.581.8008
jbflannery@jonesday.com

Attorneys for Defendant Abbott Laboratories

IN THE COURT OF COMMON PLEAS OF PHILADELPHIA COUNTY
FIRST JUDICIAL DISTRICT OF PENNSYLVANIA
TRIAL DIVISION – CIVIL

TERRAINE ABDULLAH, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	MARCH TERM, 2022 No. 220302583
HOLLI CARTER, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	MARCH TERM, 2022 No. 220302588
SHONDERA DRAYTON, et al., Plaintiff,	: :	MARCH TERM, 2022

v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	No. 220302594
BRANDY GOODMOND, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	APRIL TERM, 2022 No. 220400208
BRANDY GOODMOND, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	APRIL TERM, 2022 No. 220400212
TONYA GRAY, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	APRIL TERM, 2022 No. 220400216
JANEE HENDERSON, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	APRIL TERM, 2022 No. 220400127
DELQUAN HINES, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	 : : : :	APRIL TERM, 2022 No. 220400136
SHEMIKA JOHNSON, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	APRIL TERM, 2022 No. 220400162
KRISTEN KAJUFFA, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	: : : : :	MARCH TERM, 2022 No. 220302978
NAFEESAH MAYS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al.,	: : : :	MARCH TERM, 2022 No. 220302963

Defendants.	:	
CATHERINE McMILLIAN, et al.,	:	
Plaintiff,	:	APRIL TERM, 2022
v.	:	No. 220400140
MEAD JOHNSON & COMPANY, LLC, et al.,	:	
Defendants.	:	
DAMEKA MOMENT, et al.,	:	
Plaintiff,	:	APRIL TERM, 2022
v.	:	No. 220400142
MEAD JOHNSON & COMPANY, LLC, et al.,	:	
Defendants.	:	
ERICA PADILLA, et al.,	:	
Plaintiff,	:	MARCH TERM, 2022
v.	:	No. 220302969
MEAD JOHNSON & COMPANY, LLC, et al.,	:	
Defendants.	:	
NYDIA PARKER, et al.,		
Plaintiff,	:	MARCH TERM, 2022
v.	:	No. 220302983
MEAD JOHNSON & COMPANY, LLC, et al.,	:	
Defendants.	:	
ALEXANDRIA ROSS, et al.,	:	
Plaintiff,	:	MARCH TERM, 2022
v.	:	No. 220302981
MEAD JOHNSON & COMPANY, LLC, et al.,	:	
Defendants.	:	
LOREN SANDERS, et al.,	:	
Plaintiff,	:	APRIL TERM, 2022
v.	:	No. 220400153
MEAD JOHNSON & COMPANY, LLC, et al.,	:	
Defendants.	:	
SAMAYA SHORT, et al.,	:	
Plaintiff,	:	APRIL TERM, 2022
v.	:	No. 220400159
MEAD JOHNSON & COMPANY, LLC, et al.,	:	
Defendants.	:	
ALICE STILLS, et al.,	:	
Plaintiff,	:	MARCH TERM, 2022
v.	:	No. 220302617
MEAD JOHNSON & COMPANY, LLC, et al.,	:	
Defendants.	:	

CHRISTINA TAYLOR, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	MARCH TERM, 2022 No. 220302606
NATISHA THOMAS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	MARCH TERM, 2022 No. 220400158
TRINA WALKER-SAVAGE and CLIFTON ISAIAH SAVAGE, JR., et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	MARCH TERM, 2022 No. 220400156
JEANNATE WATSON, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	MARCH TERM, 2022 No. 220302967
ROBERT WHITFIELD, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	APRIL TERM, 2022 No. 220400145
GINA WIEGER, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	MARCH TERM, 2022 No. 220302614
GINA WIEGER, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	MARCH TERM, 2022 No. 220302601
SHANITA WIGGINS, et al., Plaintiff, v. MEAD JOHNSON & COMPANY, LLC, et al., Defendants.	:	MARCH TERM, 2022 No. 220302986
MELVENIA WILLIAMS, et al.,	:	

Plaintiff,	:	APRIL TERM, 2022
v.	:	No. 220400141
MEAD JOHNSON & COMPANY, LLC, et al.,	:	
Defendants.	:	
IVYANN WITHERSPOON, et al.,	:	
Plaintiff,	:	APRIL TERM, 2022
v.	:	No. 220400138
MEAD JOHNSON & COMPANY, LLC, et al.,	:	
Defendants.	:	

DEFENDANT ABBOTT LABORATORIES' BRIEF IN SUPPORT OF PRELIMINARY OBJECTIONS TO PLAINTIFFS' COMPLAINT

MATTER BEFORE THE COURT

The preliminary objections of Abbott Laboratories ("Abbott") to plaintiffs' complaints are before this Court.[1] Under Pennsylvania Rules of Civil Procedure 1028(a)(2), 1028(a)(3), and 1028(a)(4), Abbott respectfully requests that this Court dismiss Counts I, II, III, IV, and V of the complaints for insufficient specificity, legal insufficiency of pleading, and/or failure to conform to a rule of court.

STATEMENT OF QUESTIONS INVOLVED

1. Should the Court sustain Abbott's preliminary objections and dismiss all claims against Abbott (Counts I-V) as legally insufficient for failure to plead the product at issue is unreasonably dangerous? Answer: Yes.

2. Should the Court sustain Abbott's preliminary objections to the complaints and dismiss the strict liability claims (Counts I and II) as legally insufficient? Answer: Yes.

3. Should the Court sustain Abbott's preliminary objections to the complaints and dismiss the negligence claim (Count III) as legally insufficient? Answer: Yes.

4. Should the Court sustain Abbott's preliminary objections to the complaints and dismiss the intentional and negligent misrepresentation claims (Counts IV and V) as insufficiently pled? Answer: Yes.

[1] The substantive allegations against Abbott in all twenty-nine complaints are nearly identical. The complaint in the following eighteen cases uses identical paragraph numbering: *Abdullah; Carter; Drayton; Henderson; Hines; Johnson; McMillian; Moment; Sanders; Short; Taylor; Thomas; Walker-Savage; Whitfield; Wieger (M.P.); Wieger (S.P.); Williams; and Witherspoon*. Paragraph numbers cited in the text of these preliminary objections are to this complaint ("reference complaint") (attached as Exhibit A). Paragraph numbers for the other eleven complaints are cited in footnotes herein. For *Goodmond (Rya. G.); Goodmond (Ryh. G.); Gray; Kajuffa; Mays; Padilla; Parker; Ross; Stills; Watson; Wiggins*, the operative complaint is attached as Exhibit D.

5. Should the Court sustain Abbott's preliminary objections and dismiss the complaints as insufficiently pled for failure to properly differentiate between the defendants, or alternatively, strike all paragraphs in which plaintiffs fail to differentiate between defendants?[2] Answer: Yes.

6. Should the Court sustain Abbott's preliminary objections to the complaints and dismiss as time-barred the plaintiff-parents' claims in *Abdullah*, *Carter*, *Goodmond (Rya)*, *Goodmond (Ryh)*, *Gray*, *Henderson*, *Johnson*, *Kajuffa*, *Mays*, *McMillian*, *Moment*, *Padilla*, *Parker*, *Sanders*, *Short*, *Stills*, *Taylor*, *Thomas*, *Walker-Savage*, *Watson*, *Wieger (M.P.)*, *Wieger (S.P.)*, and *Wiggins*? Answer: Yes.

7. Should the Court sustain Abbott's preliminary objections to the complaints and strike plaintiffs' requests for punitive damages in Counts I through V as both legally insufficient and lacking sufficient specificity? Answer: Yes.

8. Should the Court sustain Abbott's preliminary objections to the complaints and strike plaintiffs' complaints for failure to conform to a rule of court? Answer: Yes.

INTRODUCTION AND FACTUAL BACKGROUND

Twenty-nine nearly identical lawsuits filed by plaintiffs in this Court attack specialized infant formulas and fortifiers essential to the survival and development of premature infants in neonatal intensive care units ("NICUs"). Mead Johnson & Company LLC, Mead Johnson Nutrition Company (together, "Mead Johnson"), and Abbott develop and manufacture infant nutrition products, including products tailored to address the distinct nutritional needs of

[2] For example, in the reference complaint, plaintiffs fail to differentiate between defendants in each of the following paragraphs: 1–2, 12–13, 26, 28–31, 33, 35, 41–43, 63, and 65–112. These allegations appear in all complaints, though paragraph numbering differs in some of the cases.

premature, low birthweight infants.[3] These infants face complex challenges and daunting odds. For one, they typically have underdeveloped or maldeveloped gastrointestinal systems that are not prepared to receive the nutrition necessary for the rapid growth these infants need. This poses a serious challenge for NICU specialists caring for the infants. The best nutrition for a premature infant is the nutrition it would have received in the womb. Once that is no longer possible, everything else falls short. Milk from the infant's mother is the closest natural substitute, but it may not be available or nutritionally sufficient to meet the premature infant's extraordinary needs. The same is true of donor milk. Accordingly, NICU specialists use their judgment to fill the nutritional gap with specialized formula and fortifier products designed to meet the needs of premature, low-birth-weight infants. This litigation targets these life-saving products.

The infants in these cases all allegedly developed necrotizing enterocolitis ("NEC"), a leading cause of death in premature infants in NICUs. NEC is an inflammatory gastrointestinal condition that can result in death of intestinal tissue. Plaintiffs admit that premature infants' underdevelopment makes them "especially susceptible to NEC." As plaintiffs acknowledge in their complaints, premature and low-birth weight infants face daunting medical challenges, such as underdeveloped gastrointestinal systems. Because of this, "[p]reterm and low-birth-weight infants are especially susceptible" to NEC. *See* Compl. ¶ 16.[4] Indeed, NEC affects up to 8% of infants in NICUs, including infants who receive only human milk, as well as those who receive no "food" at all. Neonatologists are experts in dealing with the risks of NEC and balancing them with other medical risks these premature infants face. They do so regardless of how nutrition is

[3] Abbott manufactures infant nutrition products under the "Similac" brand name. Compl. ¶ 5. Mead Johnson manufactures infant nutrition products under the "Enfamil" brand name. *Id.* ¶ 4.

[4] Same allegation found at Compl. ¶ 15: *Goodmond (Rya G.); Kajuffa; Parker; Ross; Stills; Wiggins.* Compl. ¶ 16: *Goodmond (Ryh G.); Gray; Mays; Padilla; Watson*.

administered, and regardless of whether it consists of the mother's own milk, human donor milk, specialized formula or fortifier, or a combination.

Each parent-plaintiff alleges that their child was born prematurely at a Philadelphia-area hospital. Compl. ¶ 11.[5] Their complaints allege "upon information and belief" that their child was administered "Similac and/or Enfamil cow's milk-based products" by medical professionals at the respective hospital shortly after his/her birth. *Id.* ¶ 12.[6] Plaintiffs further claim that their child developed NEC shortly after the administration of Abbott and/or Mead Johnson's product and experienced long-term health effects. *Id.* ¶¶ 13–14.[7]

Plaintiffs allege that Abbott and/or Mead Johnson manufactured and sold their products knowing that they were unreasonably dangerous and not suited for their intended use because they purportedly cause NEC, and that Abbott and/or Mead Johnson failed to warn plaintiffs and the public of this potential harm. *See* Compl. ¶¶ 68–69, 71, 77–79.[8] According to plaintiffs, Abbott and Mead Johnson also made false statements of material fact "on an ongoing and repeated basis" to consumers, physicians, and medical staff in their advertising and marketing materials prior to the time their children were administered their products. *Id.* ¶¶ 96–97.[9]

---

[5] Same allegation found at Compl. ¶ 10: *Kajuffa; Parker; Ross; Wiggins.* Compl. ¶ 11: *Goodmond (Ryh G.)*; *Goodmond (Rya G.); Gray; Mays; Padilla; Stills; Watson.*

[6] Same allegation found at Compl. ¶ 11: *Kajuffa; Parker; Ross; Wiggins.* Compl. ¶ 12: *Goodmond (Ryh G.)*; *Goodmond (Rya G.); Gray; Mays; Padilla; Stills; Watson.*

[7] Same allegation found at Compl. ¶¶ 12–13: *Kajuffa; Parker; Ross; Wiggins.* Compl. ¶¶ 13–14: *Goodmond (Ryh G.)*; *Goodmond (Rya G.); Gray; Mays; Padilla; Watson.* In the *Stills* complaint, there is no allegation of any long-term health effects resulting from the alleged NEC diagnosis.

[8] Same allegation found at Compl. ¶¶ 67–68, 70, 76–78: *Kajuffa; Mays; Padilla; Parker; Ross; Stills; Watson; Wiggins.* Compl. ¶¶ 66–67, 69, 75–77: *Goodmond (Ryh G.)*; *Gray.* Compl. ¶¶ 65–66, 68, 74–76: *Goodmond (Rya G.).*

[9] Same allegation found at Compl. ¶¶ 95–96: *Kajuffa; Mays; Padilla; Parker; Ross; Stills; Watson; Wiggins.* Compl. ¶¶ 94–95: *Goodmond (Ryh G.)*; *Gray.* Compl. ¶¶ 93–94: *Goodmond (Rya G.).*

Plaintiffs each bring five claims against Abbott and Mead Johnson: strict products liability design defect (Count I), strict products liability failure to warn (Count II), negligence (Count III), intentional misrepresentation (Count IV), and negligent misrepresentation (Count V). Plaintiffs also bring failure to warn (Count VI) and corporate liability (Count VII) claims against the hospital at which their child was born.

Noticeably absent from all of plaintiffs' complaints, however, is any identification of the products that were actually administered to their children. Although plaintiffs acknowledge that Abbott and Mead Johnson sell many different products, there are no allegations in the complaints identifying any product sold by Abbott as the specific product that was administered to any specific child. *See* Compl. ¶¶ 37–38 (describing multiple Abbott products and multiple Mead Johnson products).[10] Further, there are no allegations indicating that plaintiffs saw or were otherwise exposed to the allegedly false representations made by Abbott and/or Mead Johnson about their products. These pleading deficiencies are fatal to plaintiffs' claims.

ARGUMENT

The allegations in the complaints are legally insufficient, lack sufficient specificity, and/or fail to conform to a rule of court because:

- plaintiffs do not sufficiently allege that the product(s) at issue are unreasonably dangerous;
- plaintiffs never identify the product administered to their child;
- plaintiffs do not plead with specificity that any misrepresentations were made to them;
- plaintiffs impermissibly lump Abbott and Mead Johnson together without distinguishing the conduct purportedly attributable to each;

[10] Same allegation found at Compl. ¶¶ 36–37: *Goodmond (Rya G.); Kajuffa; Parker; Ross; Stills; Wiggins.* Compl. ¶¶ 37–38: *Goodmond (Ryh G.); Gray; Mays; Padilla; Watson.*

- plaintiff-parents' claims in 23 of the 29 actions[11] are barred by the statute of limitations;
- plaintiffs fail to plead their requests for punitive damages with the requisite legal sufficiency and factual specificity; and
- plaintiffs' complaints are not properly verified.

Accordingly, the Court should dismiss all claims against Abbott.

I. LEGAL STANDARD

Pennsylvania is a fact-pleading jurisdiction. *See generally* Pa. R. Civ. P. 1019. A complaint must therefore set forth the material facts upon which a claim is based. Pa. R. Civ. P. 1019(a). Indeed, "[t]he purpose of the pleadings is to place the defendants on notice of the claims upon which they will have to defend." *Carlson v. Cmty. Ambulance Servs.*, 824 A.2d 1228 (Pa. Super. Ct. 2003) (quoting *Yacoub v. Lehigh Valley Med.*, 805 A.2d 579, 588 (Pa. Super. 2002)). So the "complaint must give the defendants fair notice of the plaintiff's claims and a summary of the material facts that support those claims." *Carlson*, 824 A.2d 1228.

To that end, Rule 1028 of the Pennsylvania Rules of Civil Procedure provides that a party may file preliminary objections asserting that a pleading is insufficiently specific. Pa. R. Civ. P. 1028(a)(3). When assessing whether a pleading is sufficiently specific, the relevant question is "whether the complaint is sufficiently clear to enable the defendant to prepare [its] defense, or whether the plaintiff[']s complaint informs the defendant with accuracy and completeness of the specific basis on which recovery is sought so that [the defendant] may know without question upon what grounds to make [its] defense." *Rambo v. Greene*, 906 A.2d 1232 (Pa. Super. Ct. 2006).

Rule 1028 of the Pennsylvania Rules of Civil Procedure also provides that a party may file preliminary objections asserting that the pleading is legally deficient. Pa. R. Civ. P. 1028(a)(4). Generally, where a legal deficiency is "apparent on the face of the complaint," it "is needless to

[11] *See* Chart in Abbott Preliminary Objections, ¶ 33.

prolong proceedings when the matter can be correctly and quickly decided on preliminary objections in the nature of a demurrer." *Wurth v. City of Phila.*, 584 A.2d 403, 407 (Pa. Commw. Ct. 1990).

"Preliminary objections in the nature of [a] demurrer test the legal sufficiency of the plaintiff's complaint." *Sexton v. PNC Bank*, 792 A.2d 602, 604 (Pa. Super. Ct. 2002). The question presented by the demurrer is whether, on the facts alleged, no recovery is possible. *Presbyterian Med. Ctr. v. Budd*, 832 A.2d 1066, 1070 (Pa. Super. Ct. 2003) (citation omitted). In answering this question, the court is "precluded from considering any conclusions of law or inferences which are not supported by the factual allegations contained in the complaint." *Hart v. O'Malley*, 647 A.2d 542, 553 (Pa. Super. Ct. 1994). Thus, a plaintiff cannot maintain a cause of action by stating conclusions of law, argumentative allegations, and expressions of opinion. *Neill v. Eberle*, 620 A.2d 673, 675 (Pa. Commw. Ct. 1993). And a court "may not supply a fact missing [from] the complaint" in order to cure a defective pleading. *Hart*, 647 A.2d at 553.

II. PLAINTIFFS FAIL TO PLEAD FACTS SUFFICIENT TO SHOW AN UNREASONABLY DANGEROUS DEFECT, AS REQUIRED FOR COUNTS I-V.

Abbott demurs to Counts I-V under Pa. R. Civ. P. 1028(a)(4). Although plaintiffs' claims against Abbott are premised on the notion that its cow's milk-based products are unreasonably dangerous, plaintiffs fail to plead essential facts to show this is so, as required to sustain a products liability cause of action under Pennsylvania law.

"The threshold inquiry in all products liability cases is whether there is a defect which rendered the product unreasonably dangerous." *Weiner v. Am. Honda Motor Co.*, 718 A.2d 305, 307 (Pa. Super. Ct. 1998). "A product is defective when it is not safe for its intended use, i.e., the product left the supplier's control lacking any element necessary to make it safe for its intended

use." *Id.* at 308.[12] Plaintiffs must aver sufficient facts demonstrating that Abbott's products were unreasonably dangerous for their intended use, precipitating Abbott's duty to warn.

Plaintiffs fail to do so here. While plaintiffs allege that Abbott advertised its "cow's milk-based products are necessary for proper growth and development of preterm infants," *see* Compl. ¶ 43[13], plaintiffs have not alleged sufficient facts to demonstrate that these cow's milk-based products are unreasonably dangerous for this intended purpose.

Although plaintiffs rely on five studies comparing cow's milk-based products to human milk, a Surgeon General report on the subject, and a statement by the American Academy of Pediatrics, plaintiffs' reliance on these materials is misleading.[14] As plaintiffs aptly acknowledge at the outset: "[p]reterm and low-birth-weight infants are ***especially susceptible*** to NEC." *Id.* ¶ 16 (emphasis added).[15] None of the studies or research cited by plaintiffs supports the proposition that cow's milk-based feeding products ***cause*** NEC, such that they could be unreasonably dangerous when administered to premature and low birth weight infants:

---

[12] The law of product liability within Pennsylvania has developed under the principles outlined in Section 402A of the Second Restatement of Torts. *High v. Penn. Supply, Inc*., 154 A.3d 341 (Pa. Super. Ct. 2017). Specifically, Section 402(A) provides: "One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if the seller is engaged in the business of selling such a product, and it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold. The rule stated in Subsection (1) applies although the seller has exercised all possible care in the preparation and sale of his product, and the user or consumer has not bought the product from or entered into any contractual relation with the seller." RESTATEMENT OF TORTS (SECOND) § 402(A).

[13] Same allegation found at Compl. ¶ 42: *Goodmond (Rya G.); Kajuffa; Parker; Ross; Stills; Wiggins.* Compl. ¶ 43: *Goodmond (Ryh G.); Gray; Mays; Padilla; Watson.*

[14] Plaintiffs' complaints purport to rely on findings from these studies and statements, but tellingly do not provide citations. Nor do plaintiffs attach these studies or statements to their complaints. Here, because plaintiffs rely extensively on two particular studies they say conclude the product is defective, Abbott properly attaches them for the Court's consideration. *See Richardson v. Wetzel*, 74 A.3d 353, 358 n.4 (Pa. Commw. Ct. 2013) (holding that where a plaintiff has averred the existence of certain written documents and premised a cause of action upon those documents, it is proper in Pennsylvania for a defendant to attach those documents in support of a demurrer). A careful review of plaintiffs' referenced studies confirms that none of them stand for or support the proposition that cow's milk-based formula and fortifier products cause NEC.

[15] Same allegation found at Compl. ¶ 15: *Goodmond (Rya G.); Kajuffa; Parker; Ross; Stills; Wiggins.* Compl. ¶ 16: *Goodmond (Ryh G.); Gray; Mays; Padilla; Watson.*

- Plaintiffs first cite to a study reporting that "NEC was six to ten times more common in exclusively cow's milk formula-fed babies than in exclusively breast milk-fed babies and three times more common in babies who received a combination of formula and breast milk." *Id.* ¶ 17.[16] Putting aside the issues with the underlying data and design of this study, a finding that NEC is more common in infants administered cow's milk-based products than those administered human milk is not a finding of causation. Indeed, this very study simply suggests that the difference in NEC rates may result from the biologically natural protective effects of immunoglobulin in human milk, which, when consumed as the sole source of nutrition or as supplemented with formula, protect against NEC. Lucas, et al., *Breast Milk and Neonatal Necrotizing Enterocolitis*, 336 LANCET 1519, 1522 (1990) ("We suggest, in the light of the finding that oral immunoglobulin in formula fed babies was prophylactic, that breast milk may protect against necrotizing enterocolitis by providing IgA in the gut lumen.") (attached as Exhibit A).

- Plaintiffs' second study—cited for the mere proposition that "preterm babies fed an exclusive breast milk-based diet were 90% less likely to develop surgical NEC (NEC requiring surgical treatment), compared to preterm babies fed a diet that included some cow's milk-based products," Compl. ¶ 18[17]—likewise does not support the claim that cow's milk-based feeding products cause NEC. Again putting aside the issues with the underlying design of this study, at most, the study suggests that human milk is protective against NEC. Sandra Sullivan, et al., *An Exclusively Human Milk-Based Diet is Associated with a Lower Rate of Necrotizing Enterocolitis than a Diet of Human Milk and Bovine Milk-Based Products*, 4 J. PEDIAT. 562, 566 (2010) ("These data suggest that exclusive human milk diets may exert protective, rather than threshold, effects with respect to NEC.") (attached as Exhibit B).

- Plaintiffs' third study similarly makes no statements on causation and is cited for the limited proposition that "fortification of breast milk with a cow's milk-based fortifier resulted in a 4.2-fold increased risk of NEC and a 5.1-fold increased risk of surgical NEC or death, compared to fortification with a breast milk-based fortifier." Compl. ¶ 19.[18]

- The Surgeon General report cited by plaintiffs reiterates the findings in the aforementioned three studies and merely states that "formula feeding is associated with *higher rates"* of NEC in premature infants. *See id.* at ¶ 20 (emphasis added).[19]

---

[16] Same allegation found at Compl. ¶ 16: *Goodmond (Rya G.); Kajuffa; Parker; Ross; Stills; Wiggins.* Compl. ¶ 17: *Goodmond (Ryh G.); Gray; Mays; Padilla; Watson.*

[17] Same allegation found at Compl. ¶ 17: *Goodmond (Rya G.); Kajuffa; Parker; Ross; Stills; Wiggins.* Compl. ¶ 18: *Goodmond (Ryh G.); Gray; Mays; Padilla; Watson.*

[18] Same allegation found at Compl. ¶ 18: *Goodmond (Rya G.); Kajuffa; Parker; Ross; Stills; Wiggins.* Compl. ¶ 19: *Goodmond (Ryh G.); Gray; Mays; Padilla; Watson.*

[19] Same allegation found at Compl. ¶ 19: *Goodmond (Rya G.); Kajuffa; Parker; Ross; Stills; Wiggins.* Compl. ¶ 20: *Goodmond (Ryh G.); Gray; Mays; Padilla; Watson.*

Yet again, this report does not state that cow's milk-based formula causes NEC; instead, it acknowledges that all premature infants are highly susceptible to NEC, regardless of their diet.

- The American Academy of Pediatrics report—recommending that "all premature infants should be fed either their mother's milk or, if their mother's milk is unavailable, pasteurized donor milk," *id.* at ¶ 21[20]—expressly acknowledges that NEC still occurs in premature infants administered only human milk, albeit at a lower rate. Although AAP reports the "potent protective effects of breastmilk," nowhere does it state that cow's milk-based feeding products cause NEC. *Id.*

- And finally, like the other studies, the fourth and fifth studies cited by plaintiffs do not conclude that cow's milk-based formula causes NEC. *Id.* ¶¶ 22-23 (one study "found that premature and low-birth-weight infants fed an exclusive breast-milk-based diet suffered NEC only 3% of the time while premature and low-birth-weight infants receiving cow's milk-based formula suffered NEC 21% of the time," and the other stated that "babies given exclusively breast milk products suffered NEC 5% of the time," whereas "babies given cow's milk products suffered NEC 17% of the time."). [21] These studies again do no more than provide further evidence that human milk is protective against NEC; not that cow's milk-based products cause NEC.

Thus, plaintiffs' allegations that Abbott's cow's milk-based feeding products "cause" NEC and are therefore "unreasonably dangerous" rest upon studies and reports showing merely that human milk is protective against NEC—not a causal relationship between cow's milk-based feeding products and NEC. Indeed, plaintiffs concede that all premature, low birthweight infants are especially susceptible and at high risk of developing NEC, regardless of their diet (including those who are administered human milk exclusively). Because plaintiffs only plead, at most, facts sufficient to support that breast milk may be protective against the risk of NEC, not that cow's milk-based alternatives cause NEC, plaintiffs fail to allege facts sufficient to show that Abbott's

[20] Same allegation found at Compl. ¶ 20: *Goodmond (Rya G.); Kajuffa; Parker; Ross; Stills; Wiggins.* Compl. ¶ 21: *Goodmond (Ryh G.); Gray; Mays; Padilla; Watson.*

[21] Same allegation found at Compl. ¶¶ 21-22: *Goodmond (Rya G.); Kajuffa; Parker; Ross; Stills; Wiggins.* Compl. ¶¶ 22-23: *Goodmond (Ryh G.); Gray; Mays; Padilla; Watson.*

products were unreasonably dangerous, as required to maintain a product liability cause of action under Pennsylvania law.

III. PLAINTIFFS FAIL TO SUFFICIENTLY PLEAD THEIR STRICT LIABILITY CLAIMS (COUNTS I–II).

Plaintiffs fail to allege sufficient facts to support their strict liability claims (Counts I and II) because plaintiffs fail to identify the specific product that caused their injuries. It is well-settled that, in order to plead a strict liability claim in Pennsylvania, the "plaintiff must [] at least designate the product alleged to be defective[.]" *Cummins v. Firestone Tire & Rubber Co.*, 495 A.2d 963, 969 (Pa. Super. Ct. 1985).

Plaintiffs fail to do so here. Instead, plaintiffs broadly allege that Abbott manufactures and sells products under the Similac or Enfamil brand names, Compl. ¶ 5, 12[22] and surmise "upon information and belief" that their child was administered "Similac and/or Enfamil" products, *id.* ¶¶ 12, 74.[23] These allegations are plainly insufficient. As plaintiffs acknowledge, Abbott and Mead Johnson each sell many different products. *See, e.g.*, Compl. ¶¶ 37–38[24] (describing multiple Abbott products and multiple Mead Johnson products). However, the complaints are devoid of any facts identifying the specific product that allegedly caused plaintiffs' injuries, including product identification information from any of plaintiff's medical records. As such, even viewing the complaints in the light most favorable to plaintiffs, their strict liability claims fail. *See Cummins*, 495 A.2d at 968–69 (holding that the plaintiff's failure to identify the offending product was "a fatal deficiency to his [strict liability] claim" and that "the complaint [could] not adequately aver the requisite connection between the [defendants] and the defective product"); *Klein v. Council of*

[22] Same allegations found at Compl. ¶¶ 5, 11: *Kajuffa; Parker; Ross; Wiggins.*

[23] Same allegations found at Compl. ¶¶ 11, 73: *Kajuffa; Parker; Ross; Wiggins.* Compl. ¶¶ 12, 73: *Mays; Padilla; Stills; Watson.* Compl. ¶¶ 12, 71: *Goodmond (Rya G.)*; Compl. ¶¶ 12, 72: *Goodmond (Ryh G.); Gray.*

[24] Same allegation found at Compl. ¶¶ 36–37: *Goodmond (Rya G.); Kajuffa; Parker; Ross; Stills; Wiggins.* Compl. ¶¶ 37–38: *Goodmond (Ryh G.)*; *Gray; Mays; Padilla; Watson.*

Chem. Assocs., 587 F. Supp. 213, 221 (E.D. Pa. 1984) (dismissing strict liability claim where plaintiffs did not identify the specific product sold or distributed by the defendants that caused the plaintiffs' harm).[25]

IV. PLAINTIFFS FAIL TO SUFFICIENTLY PLEAD A NEGLIGENCE CLAIM (COUNT III).

Plaintiffs' negligence claim fails for the same reason as their strict liability claims do: they simply fail to identify the product that allegedly caused their injuries. To state a negligence-based products liability claim, "the plaintiff must identify the defendant as the manufacturer or seller of *the offending product* before a plaintiff's injuries may be found to be proximately caused by the negligence of the defendant." *Long v. Krueger, Inc.*, 686 F. Supp. 514, 517 (E.D. Pa. 1988) (citing *Cummins*, 495 A.2d at 967). "Absent such identification, there can be no allegations of duty, breach of duty or legal causation, and hence there can be no liability." *Cummins*, 495 A.2d at 967–68.

As noted above, plaintiffs allege only "upon information and belief" that their child was administered "Similac and/or Enfamil" products and developed NEC shortly thereafter. Compl. ¶¶ 12–13, 74.[26] Plaintiffs do not, however, identify the exact product (if any) made by Abbott giving rise to their claims. Accordingly, they "cannot allege a casual [sic] connection between conduct of the defendants and [plaintiff's] injuries." *Klein*, 587 F. Supp. at 223; *see also Cummins*, 495 A.2d

[25] Plaintiffs' strict liability claims fail for the related reason that they do not allege a sale or other commercial transfer of the specific product that allegedly caused their injuries, as required by Pennsylvania law. *Cummins*, 495 A.2d at 968. Plaintiffs allege "on information and belief" that Abbott and/or Mead Johnson provided products to hospital defendants "for free or at significant discount." *See, e.g.,* Compl. ¶ 62. They further allege that Abbott and/or Mead Johnson were "authorized" to sell their products at hospital defendants. *See.* ¶¶ 118, 131–32. But there are no allegations that Abbott and/or Mead Johnson's products generally—or the product administered to plaintiff specifically—were actually sold to hospital defendants. Because plaintiffs fail to allege any underlying commercial sale or transaction of the product that purportedly caused harm, their strict liability claims warrant dismissal. *See Cummins*, 495 A.2d at 968–69 (reasoning that plaintiff's strict liability claim failed because he could not identify the manufacturer of the product that allegedly injured him and was thus unable to establish that the defendant made the requisite sale or other commercial transfer).

[26] Same allegation found at Compl. ¶¶ 11–12, 73: *Kajuffa; Parker; Ross; Wiggins.* Compl. ¶¶ 12–13, 73: *Mays; Padilla; Stills; Watson*. Compl. ¶¶ 12–13, 72: *Goodmond (Ryh G.); Gray.* Compl. ¶¶ 12–13, 71: *Goodmond (Rya G.)*.

at 967 (affirming dismissal of negligence claim where plaintiff failed to identify a specific product and the identity of the manufacturer, supplier, or seller of the product; and therefore did not establish a causal connection between his injury and the defendants' conduct).

V. PLAINTIFFS FAIL TO PLEAD THEIR INTENTIONAL AND NEGLIGENT MISREPRESENTATION CLAIMS (COUNTS IV–V) WITH SUFFICIENT PARTICULARITY.

Plaintiffs' intentional and negligent misrepresentation claims fail because plaintiffs do not plead facts supporting these claims with sufficient particularity. To state a claim for intentional misrepresentation, plaintiffs must plead: (1) a representation; (2) which is material to the transaction at hand; (3) made falsely, with knowledge of its falsity or recklessness as to whether it is true or false; (4) with the intent of misleading another into relying on it; (5) justifiable reliance on the misrepresentation; and (6) the resulting injury was proximately caused by the reliance. *Bortz v. Noon*, 556 Pa. 489, 499, 729 A.2d 555, 560 (Pa. 1999) (internal citation omitted). Similarly, to state a claim for negligent misrepresentation, plaintiffs must plead facts showing (1) a misrepresentation of a material fact; (2) that the representor either knew or should have known of the misrepresentation; (3) that the representor intended the representation to induce another to act; and (4) that injury resulted to the party acting in justifiable reliance on the misrepresentation. *See id.* at 561.

Furthermore, in order to protect against generalized and unsupported accusations of fraud, the Pennsylvania Rules of Civil Procedure require that claims involving fraud—including misrepresentation claims—be "averred with particularity." *Presbyterian Med. Ctr.*, 832 A.2d at 1072 (citing Pa. R. Civ. P. 1019(b)); *see also Dwyer v. Rothman*, 431 A.2d 1035, 1037 (Pa. Super. Ct. 1981) (applying that requirement to an intentional misrepresentation claim); *Bethpage Fed. Credit Union v. Abraham Bhatti*, 2019 WL 5303904, at *2 (Pa. Com. Pl. Oct. 17, 2019) (applying the particularity requirement to a negligent misrepresentation claim). "Merely alleging fraud as a

legal conclusion adds nothing if it is not based upon facts clearly and explicitly set forth as constituting such fraud." *Dwyer*, 431 A.2d at 1037.

The allegations in plaintiffs' complaints do not clear Rule 1019(b)'s heightened bar. *First*, while plaintiffs generally allege that Abbott made false representations in its marketing materials, *see id.* ¶¶ 97, 107,[27] plaintiffs do not allege that Abbott made any of these representations directly to them, or that they read, saw, were otherwise exposed to, or justifiably relied on any specific product label or any other specific representation from Abbott before their child was administered Abbott's products. Accordingly, plaintiffs fail to plead facts showing that their child's injuries were caused by their reliance on Abbott's representations. *See, e.g.*, *Rivello v. N.J. Auto. Full Ins. Underwriting Ass'n*, 638 A.2d 253, 257 (Pa. Super. Ct. 1994) (affirming dismissal of misrepresentation claim where plaintiff failed to sufficiently allege justifiable reliance on the alleged misrepresentation or that his injury was proximately caused by the alleged misrepresentation); *Youndt v. First Nat'l Bank*, 868 A.2d 539 (Pa. Super. Ct. 2005) (holding fraud claim failed where plaintiff did not plead all elements with particularity); *Feudale v. Aqua Pa., Inc.*, 122 A.3d 462, 466 n.5 (Pa. Commw. Ct. 2015) (concluding that plaintiff had failed to "allege[ ] any justifiable reliance on his part on the [alleged false representation], nor could he, as the alleged false representation was not made to him, but instead to [a third party]"); *Feingold v. Unitrin Direct*, 2012 WL 3866945, at *6 (E.D. Pa. Sept. 6, 2012) (dismissing negligent misrepresentation claim where plaintiff could not allege that he justifiably relied on the defendants' promises).

[27] Same allegation found at Compl. ¶96, 106: *Kajuffa; Mays; Padilla; Parker; Ross; Stills; Watson; Wiggins.* Compl. ¶¶ 95, 105: *Goodmond (Ryh G.)*; *Gray.* Compl. ¶¶ 94, 104: *Goodmond (Rya G.).*

Second, plaintiffs do not identify when the alleged misrepresentations were made, what specific marketing materials contained the misrepresentations, or who made them. As such, the allegations in the complaints cannot plausibly support plaintiffs' intentional misrepresentation claim. *See, e.g.*, *Dwyer*, 431 A.2d at 1037 (affirming lower court's decision sustaining preliminary objections to plaintiff's intentional misrepresentation claim where plaintiff did not allege what facts were misrepresented, what false information was given, nor in what way he was "tricked"); *Presbyterian Med. Ctr.*, 832 A.2d at 1073 (affirming order sustaining preliminary objections to complaint where plaintiff failed to "establish every element of its fraud claim with sufficient particularity"). Plaintiffs' allegations are likewise woefully deficient to support their negligent misrepresentation claim, which should be dismissed on that basis as well. *See, e.g.*, *Bethpage Fed. Credit Union*, 2019 WL 5303904, at *2 (sustaining preliminary objections to fraud and negligent misrepresentation claims due to plaintiff's failure to satisfy Rule 1019(b)'s particularity requirements); *Black v. Cmty. Educ. Ctrs., Inc.*, 2014 WL 859313, at *6 (E.D. Pa. Mar. 4, 2014) (finding plaintiff's claims of misrepresentation and fraud failed because she did not allege the instances of mischaracterization with specificity); *Scott v. Bimbo Bakeries, USA, Inc.*, 2012 WL 645905, at *6 (E.D. Pa. Feb. 29, 2012) (dismissing negligent misrepresentation claim where plaintiffs did not "allege when these alleged misrepresentations were made, who made them, or how they were communicated").

VI. PLAINTIFFS' FAILURE TO DIFFERENTIATE CLAIMS BETWEEN ABBOTT AND MEAD JOHNSON WARRANTS DISMISSAL OF COUNTS I-V.

All of plaintiffs' claims against Abbott are insufficiently pled for yet another reason: plaintiffs fail to differentiate between Abbott and Mead Johnson. Rule 1019(a) of the Pennsylvania Rules of Civil Procedure provides that a complaint must set forth the material facts upon which a claim is based. Pa. R. Civ. P. 1019(a). And "even under the most liberal notice pleading

requirements," that means that "a plaintiff must differentiate between defendants." *Coyne v. Holy Fam. Apartments*, 2020 WL 2063475, at *4 (E.D. Pa. Apr. 29, 2020); *see also Bouchon v. Citizen Care, Inc.*, 176 A.3d 244, 260 (Pa. Super. Ct. 2017) (affirming dismissal of complaint where several paragraphs of the complaint did not differentiate between the defendants in averring the conduct and claims).

Despite this clear law, plaintiffs' complaints are riddled with allegations about the conduct of "Defendant Manufacturers," or "Abbott and/or Mead Johnson." *See, e.g.,* Compl. ¶¶ 1–2, 12–13, 26, 28–31, 33, 35, 41–43, 63, and 65–112. But the complaints do not allege any facts establishing which specific product from which specific manufacturer gave rise to plaintiffs' claims. Abbott is left to guess what role plaintiffs believe it played in the events at issue placing a burden on Abbott that is not contemplated or condoned by Pennsylvania's fact pleading rules. Because plaintiffs fail to distinguish between defendants throughout their complaints, all claims against Abbott should be dismissed, or alternatively, the paragraphs in which plaintiffs fail to differentiate between defendants should be stricken.[28]

VII. PLAINTIFF-PARENT'S CLAIMS IN 23 CASES ARE BARRED BY THE STATUTE OF LIMITATIONS.

Plaintiff-parents' claims in 23 of the 29 cases[29] are time-barred. Pennsylvania law sets a two-year statute of limitations on actions to recover damages for personal injury based on negligent, intentional, or otherwise tortious conduct. *See* 42 Pa. Cons. Stat. § 5524(2) & (7). Twenty-three of the 29 complaints allege birth dates between August 9, 2002 (*Walker-Savage*)

[28] For example, in the reference complaint, plaintiffs fail to differentiate between defendants in each of the following paragraphs: 1–2, 12–13, 26, 28–31, 33, 35, 41–43, 63, and 65–112. These allegations are identical across all 29 actions, though paragraph numbering may differ from action to action.

[29] *See* Chart in Abbott Preliminary Objections, ¶ 33.

and November 30, 2017 (*Moment*). Compl. ¶¶ 11.[30] In each, plaintiffs allege that their children developed NEC shortly after birth, after being administered Abbott and/or Mead Johnson's products. Compl. ¶¶ 12–13.[31] But their complaints were not filed until sometime between March 24, 2022 and April 4, 2022—well after the limitations period expired. Notably, they were untimely filed even though plaintiffs allege that publicly available information about NEC and the risks and benefits associated with formula versus breastmilk feeding has been available for decades. *See id.* ¶¶ 34.[32] Consequently, plaintiff-parents' claims are time-barred and must be dismissed. *See, e.g.*, *Hathi v. Krewstown Park Apartments*, 561 A.2d 1261, 1263 (Pa. Super. Ct. 1989); *Sayers v. Heritage Valley Md. Grp., Inc*., 247 A.3d 1155, 1159-63 (Pa. Super. Ct. 2021).

VIII. PLAINTIFFS' FAIL TO PLEAD THEIR REQUESTS FOR PUNITIVE DAMAGES WITH THE REQUISITE LEGAL SUFFICIENCY AND FACTUAL SPECIFICITY.

Plaintiffs' requests for punitive damages should be stricken, as their demands are both legally and factually insufficient, and fail to clear the high bar for punitive damages under Pennsylvania law. In Pennsylvania, "'[p]unitive damages' are damages other than compensatory or nominal damages awarded against a person to punish him for his outrageous conduct." *See Focht v. Rabada*, 268 A.2d 157, 159 (Pa. Super. Ct. 1970) (quoting RESTATEMENT OF TORTS § 908(1)). "As the name suggests, punitive damages are penal in nature and are proper only in cases where the defendant's actions are so outrageous as to demonstrate willful, wanton or reckless conduct." *Hutchison v. Luddy*, 870 A.2d 766, 770 (2005); *see also Phillips v. Cricket Lighters*, 883 A.2d 439, 446 (2005) ("Punitive damages may be appropriately awarded only when the plaintiff

[30] Date of birth allegation found at Compl. ¶ 10: *Kajuffa; Parker; Ross; Wiggins.* Compl. ¶ 11: *Goodmond (Rya G.)*; *Goodmond (Ryh G.); Gray; Mays; Padilla; Stills; Watson.*

[31] Same allegation found at Compl. ¶¶ 11–12: *Kajuffa; Parker; Ross; Wiggins.* Compl. ¶¶ 12–13: *Goodmond (Rya G.)*; *Goodmond (Ryh G.); Gray; Mays; Padilla; Stills; Watson.*

[32] Same allegation found at Compl. ¶ 33: *Goodmond (Rya G.); Kajuffa; Parker; Ross; Stills; Wiggins.* Compl. ¶ 34: *Goodmond (Ryh G.); Gray; Mays; Padilla; Watson*.

has established that the defendant has acted in an outrageous fashion due to either the defendant's evil motive or his reckless indifference to the rights of others."). To support a request for punitive damages, the plaintiff must sufficiently allege that "(1) a defendant had a subjective appreciation of the risk of harm to which the plaintiff was exposed and that (2) he acted, or failed to act, as the case may be, in conscious disregard of that risk." *Luddy*, 870 A.2d at 772.

Conduct is "willful" when "the actor desired to bring about the result that followed, or at least was aware that it was substantially certain to ensue." *Evans v. Philadelphia Transp. Co.*, 212 A.2d 440, 443 (Pa. 1965). Moreover, "reckless indifference," interchangeable with "wanton" misconduct, occurs when "the actor has intentionally done an act of an unreasonable character, in disregard to a risk known to him or so obvious that he must be taken to have been aware of it, and so great as to make it highly probable that harm would follow." *McClellan v. Health Maintenance Org. of Pa.*, 604 A.2d 1053, 1061 (1992); *see also Smith v. Brown*, 423 A.2d 743, 745 (1980) (quoting *Evans*, 212 A.2d at 443).

To begin, plaintiffs' requests for punitive damages with respect to Count III (negligence) and Count V (negligent misrepresentation) are wholly improper. As Pennsylvania law makes clear, "[p]unitive damages may not be awarded for misconduct which constitutes ordinary negligence . . . ." *See Martin v. Johns-Manville Corp.*, 494 A.2d 1088, 1097 (Pa. 1985) (citing RESTATEMENT OF TORTS (SECOND) § 908, comment e)). Here, by plaintiffs' own admission, Counts III and V sound plainly in ordinary negligence, and are thus legally insufficient. *See* Compl. ¶ 87 ("Abbott and Mead, directly or indirectly, ***negligently***, and/or defectively made, created, manufactured, designed, assembled, tested, marketing, sold, and/or distributed the cow's milk-based infant products at issue in this litigation and thereby breached their duty to the general public and Plaintiff

Parent.")[33] (emphasis added); *id.* at ¶ 108 ("Abbott and Mead were ***negligent*** or careless in not determining those representations to be false.")[34] (emphasis added).

Plaintiffs' requests for punitive damages in each of Counts I through V also fail because they are pleaded with insufficient specificity. Plaintiffs make no effort to provide factual support for their requests for punitive damages against Abbott. Instead, plaintiffs baldly and repeatedly demand judgment "[f]or punitive damages . . . resulting from the Defendant' Manufacturers' oppressive, fraudulent, and/or malicious conduct . . . ." *See* Compl. at Count I (prayer for relief); *id.* at Count II (prayer for relief); *id.* at Count III (prayer for relief); *id.* at Count VI (prayer for relief); *id.* at Count V (prayer for relief). Nowhere do plaintiffs support these bald assertions of "malicious" conduct.

At most, plaintiffs allege that Abbott "knew (or reasonably should have known) that use of their cow's milk-based products significantly increased the risk of NEC, *see*, *e.g.*, Compl. ¶ 69,[35] but such allegations are woefully insufficient. Plaintiffs cannot merely incant the word "knowledge" and make it so; rather, plaintiffs must provide factual support for their bald assertions. *See Whiting v. Nationwide Ins. Co.*, 9 Pa. D. & C.3d 789, 792 (1979) (dismissing plaintiffs' punitive damages request where "factual averments in support of . . . conclusory allegations are totally lacking"). Plaintiffs fail to do so here.[36]

---

[33] Same allegation found at Compl. ¶ 86: *Kajuffa; Mays; Padilla; Parker; Ross; Stills; Watson; Wiggins.* Compl. ¶ 85: *Goodmond (Ryh G.)*; *Gray.* Compl. ¶ 84: *Goodmond (Rya G.).*

[34] Same allegation found at Compl. ¶ 107: *Kajuffa; Mays; Padilla; Parker; Ross; Stills; Watson; Wiggins.* Compl. ¶ 106: *Goodmond (Ryh G.)*; *Gray.* Compl. ¶ 105: *Goodmond (Rya G.).*

[35] Same allegation found at Compl. ¶ 68: *Kajuffa; Mays; Padilla; Parker; Ross; Stills; Watson; Wiggins.* Compl. ¶ 67: *Goodmond (Ryh G.)*; *Gray.* Compl. ¶ 66: *Goodmond (Rya G.).*

[36] To the extent plaintiffs wish to allege that Abbott "reasonably should have known" about the alleged risks of NEC based on plaintiffs' ***own characterizations*** of the studies they quote from in their complaints, the Court should reject plaintiffs' effort. Plaintiffs have alleged no facts to support that Abbott knew of the studies to which plaintiffs quote, let alone that Abbott was aware of, or should have known of, plaintiffs' ***characterizations*** of the results of said studies. It is worth noting that, while plaintiffs quote from these studies, they do not cite to them anywhere in their complaints.

For all these reasons, Abbott respectfully requests that this Court strike plaintiffs' requests for punitive damages as wholly conclusory, lacking the requisite factual specificity, and legally insufficient.

IX. PLAINTIFFS' FAIL TO PROPERLY VERIFY THEIR COMPLAINTS UNDER RULE 1024(C).

Finally, plaintiffs' complaints should also be stricken because they are not properly verified. Rule 1024 mandates that "[e]very pleading containing an averment of fact not appearing of record in the action . . . shall state that the averment . . . is true upon the signer's personal knowledge or information and belief and shall be verified." *See* Pa. R. Civ. P. 1024(a). Subsection (c) of the Rule also explicitly mandates that

> [t]he verification shall be made by one or more of the parties filing the pleading unless all the parties (1) lack sufficient knowledge or information, or (2) are outside the jurisdiction of the court and the verification of none of them can be obtained within the time allowed for filing the pleading. *In such cases, the verification may be made by any person having sufficient knowledge or information and belief and shall set forth the source of the person's information as to matters not stated upon his or her own knowledge and the reason why the verification is not made by a party*.

See id. at 1024(c) (emphasis added).

Plaintiffs' complaints are not verified by plaintiffs themselves; rather, they are signed by their counsel. *See* verification page of each complaint. Although Rule 1024(c) expressly requires that in instances like these, where a verification is made by someone other than the filing party, the reason why the verification is not made by the party must be provided, no such explanation is provided here. Because plaintiffs' complaints do not include the proper verification, they should be stricken for failure to comply with Pa. R. Civ. P. 1028(a)(2) and 1024(c).

CONCLUSION

For the foregoing reasons, Abbott's preliminary objections to plaintiffs' complaints should be sustained, and plaintiffs' claims against Abbott should be dismissed.

Dated: June 12, 2023

Respectfully Submitted:

/s/ Sean P. Fahey
Sean P. Fahey (PA Bar No. 73305)
TROUTMAN PEPPER HAMILTON SANDERS LLP
3000 Two Logan Square
Philadelphia, PA 19103
215.981.4296
Sean.Fahey@troutman.com

/s/ Ronni E. Fuchs
Ronni E. Fuchs (PA Bar No. 65561)
TROUTMAN PEPPER HAMILTON SANDERS LLP
301 Carnegie Center, Suite 400
Princeton, NJ 08540
609.951.4183
Ronni.Fuchs@troutman.com

/s/ Joseph E. O'Neil
Joseph E. O'Neil (PA Bar No. 29053)
Meaghann C. Porth (PA Bar No. 307629)
Ryan J. O'Neil (PA Bar No. 314034)
CAMPBELL CONROY & O'NEIL, P.C.
1205 Westlakes Drive, Suite 330
Berwyn, PA 19312
610.964.6388
JONeil@CampbellTrialLawyers.com
MPorth@campbell-trial-lawyers.com
RONeil@campbell-trial-lawyers.com

/s/ Marques Hillman Richeson
Marques Hillman Richeson (admitted *pro hac vice*)
JONES DAY
901 Lakeside Avenue
Cleveland, OH 44114
216.586.7195
mhricheson@jonesday.com

/s/ Jennifer B. Flannery
Jennifer B. Flannery (PA Bar No. 74546)
JONES DAY
1221 Peachtree Street, N.E., Suite 400
Atlanta, GA 30361
404.581.8008
jbflannery@jonesday.com

Attorneys for Defendant Abbott Laboratories

CERTIFICATE OF SERVICE

I hereby certify that I will serve a true and correct copy of the foregoing in accordance with Pa. R. Civ. P. 440 on all parties not served electronically. All other parties will be electronically served by the court in accordance with Pa. R. Civ. P. 205.4(g).

Dated: June 12, 2023

/s/ Ronni E. Fuchs
Ronni E. Fuchs

CERTIFICATE OF COMPLIANCE

I, Ronni E. Fuchs, hereby certify that this filing complies with the provisions of the Public Access Policy of the Unified Judicial System of Pennsylvania: Case Records of the Appellate and Trial Courts, that require filing confidential information and documents differently than non-confidential information and documents.

/s/ Ronni E. Fuchs
Ronni E. Fuchs

EXHIBIT A

ANAPOL WEISS
BY: TRACY FINKEN, ESQUIRE
Identification Number: 82258
One Logan Square
130 N. 18th Street, Suite 1600
Philadelphia, PA 19103
(215) 735-0773
tfinken@anapolweiss.com — **ATTORNEY FOR PLAINTIFFS**

KELLER LENKNER LLC
BY: Ashley Keller (*pro hac vice forthcoming*)
150 N. Riverside Plaza, Suite 4100
Chicago, Illinois 60606
Telephone: (312) 741-5220
Fax: (312) 971-3502
Email: ack@kellerlenkner.com — **ATTORNEY FOR PLAINTIFFS**

WALSH LAW PLLC
BY: Alex Walsh (*pro hac vice forthcoming*)
1050 Connecticut Ave, NW, Suite 500
Washington, D.C. 20036
Telephone: (202) 780-4127
Fax: (202) 780-3678
Email: awalsh@alexwalshlaw.com — **ATTORNEY FOR PLAINTIFFS**

TERRAINE ABDULLAH, on her own Behalf and as Parent and Natural Guardian of H.S., a Minor **335 Passmore Street** **Philadelphia, PA 19111** **Plaintiffs**	:	**COURT OF COMMON PLEAS** **PHILADELPHIA COUNTY**
v.	:	**CIVIL ACTION**
MEAD JOHNSON & COMPANY, LLC **Illinois Corporation Service Co.** **801 Adlai Stevenson Drive** **Springfield, IL 62703**	:	**NO.**
MEAD JOHNSON NUTRITION COMPANY **Illinois Corporation Service Co.** **801 Adlai Stevenson Drive** **Springfield, IL 62703**	:	
ABBOTT LABORATORIES	:	

CT Corporation System **208 So. Lasalle Street, Suite 814** **Chicago, IL 60604**	:	
THE PENNSYLVANIA HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM d/b/a PENNSYLVANIA HOSPITAL **3400 Civic Center Blvd.** **Philadelphia, PA 19104**	:	
THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA d/b/a PENN MEDICINE **133 South 36th Street** **Philadelphia, PA 19104**	:	
Defendants	:	**JURY TRIAL DEMANDED**

COMPLAINT IN CIVIL ACTION

NOTICE TO DEFEND

NOTICE

You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER OR CANNOT AFFORD ONE, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW TO FIND OUT WHERE YOU CAN GET LEGAL HELP.

PHILADELPHIA BAR ASSOCIATION
LAWYER REFERRAL AND INFORMATION SERVICE
ONE READING CENTER
PHILADELPHIA, PA 19107
TELEPHONE: (215) 238-1701

AVISO

Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas expuestas las páginas siguientes, usted tiene viente (20) dias de plazo al partir de la fecha de la demanda y la notificación. Hace falta asentar una comparencia escrita o en persona o con un abogado y entregar a la corte en forma escrita sus defensas o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomará medidas y puede continuar la demanda en contra suya sin previo aviso o notificación. Además, la corte puede decidir a favor del demandante y requiere que usted cumpla con todas las provisiones de esta demanda. Usted puese perder dinero o sus propiedades u ostros derechos importantes para usted.

LLEVE ESTA DEMANDA A UN ABOGADO IMMEDIATAMENTE. SI NO TIENE ABOGADO O SI NO TIENE EL DINERO SUFICIENTE DE PAGAR TAL SERVICO, VAYA EN PERSONA O LLAME POR TELEPHONO A LA OFICINA CUYA DIRECCION SE ENCUENTRA ESCRITA ABAJO PARA AVERIGUAR DONDE SE PUEDE CONSEGUIR ASISTENCIA LEGAL.

ASOCIACION DE LICENCIADOS DE FILADELFIA
Servicio De Referencia E Información Legal
One Reading Center
Filadelfia, Pennsylvania 19107
Telephono: (215) 238-1701

ANAPOL WEISS
BY: TRACY FINKEN, ESQUIRE
IDENTIFICATION NUMBER: 82258
ONE LOGAN SQUARE
130 N. 18TH STREET, SUITE 1600
PHILADELPHIA, PA 19103
(215) 735-0773
TFINKEN@ANAPOLWEISS.COM — **ATTORNEY FOR PLAINTIFFS**

KELLER LENKNER LLC
BY: ASHLEY KELLER (*PRO HAC VICE FORTHCOMING*)
150 N. RIVERSIDE PLAZA, SUITE 4100
CHICAGO, ILLINOIS 60606
TELEPHONE: (312) 741-5220
FAX: (312) 971-3502
EMAIL: ACK@KELLERLENKNER.COM — **ATTORNEY FOR PLAINTIFFS**

WALSH LAW PLLC
BY: ALEX WALSH (*PRO HAC VICE FORTHCOMING*)
1050 CONNECTICUT AVE, NW, SUITE 500
WASHINGTON, D.C. 20036
TELEPHONE: (202) 780-4127
FAX: (202) 780-3678
EMAIL: AWALSH@ALEXWALSHLAW.COM — **ATTORNEY FOR PLAINTIFFS**

TERRAINE ABDULLAH, ON HER OWN BEHALF AND AS PARENT AND NATURAL GUARDIAN OF H.S., A MINOR **335 PASSMORE STREET** **PHILADELPHIA, PA 19111** **PLAINTIFFS**	:	**COURT OF COMMON PLEAS** **PHILADELPHIA COUNTY**
V.	:	**CIVIL ACTION**
MEAD JOHNSON & COMPANY, LLC **ILLINOIS CORPORATION SERVICE CO.** **801 ADLAI STEVENSON DRIVE** **SPRINGFIELD, IL 62703**	:	**NO.**
MEAD JOHNSON NUTRITION COMPANY **ILLINOIS CORPORATION SERVICE CO.** **801 ADLAI STEVENSON DRIVE** **SPRINGFIELD, IL 62703**	:	
ABBOTT LABORATORIES **CT CORPORATION SYSTEM** **208 SO. LASALLE STREET, SUITE 814** **CHICAGO, IL 60604**	:	
THE PENNSYLVANIA HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM D/B/A PENNSYLVANIA	:	

HOSPITAL **3400 CIVIC CENTER BLVD.** **PHILADELPHIA, PA 19104**	:	
THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA D/B/A PENN MEDICINE **133 SOUTH 36TH STREET** **PHILADELPHIA, PA 19104**	:	
DEFENDANTS	:	**JURY TRIAL DEMANDED**

COMPLAINT

Plaintiff brings this Complaint and Demand for Jury Trial (the "Complaint") against Mead Johnson & Company, LLC, Mead Johnson Nutrition Company, and Abbott Laboratories (collectively "the Defendant Manufacturers"), and The Trustees of the University of Pennsylvania d/b/a Penn Medicine and Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital (collectively "Penn Medicine" or "Pennsylvania Hospital"), together "Defendants." Plaintiff alleges the following upon personal knowledge as to Plaintiff's own acts and experiences and upon information and belief, including investigation conducted by Plaintiff's attorneys, as to all other matters.

I. INTRODUCTION

1. This action arises out of the injuries suffered by a premature infant (the "Injured Infant") who was given the Defendant Manufacturers' cow's milk-based infant feeding products at Pennsylvania Hospital. Pennsylvania Hospital, managed by Penn Medicine, acquired and supplied the Defendant Manufacturers' products to the Injured Infant and negligently failed to warn of their unreasonably dangerous properties in a reasonable manner. This caused the Injured Infant to develop necrotizing enterocolitis ("NEC"), a life-altering and potentially deadly disease that largely affects premature babies who are given cow's milk-based feeding products. As a result,

the Injured Infant was seriously injured, resulting in long term health effects and accompanying harm to their parent ("the Plaintiff Parent").

2. Plaintiff brings these causes of action against Defendants to recover for injuries that are the direct and proximate result of the Injured Infant's consumption of the Defendant Manufacturers' unreasonably dangerous cow's milk-based infant feeding products, which were acquired and supplied without adequate warning to the Injured Infant at Pennsylvania Hospital, owned and operated by Penn Medicine.

II. PARTIES

3. Plaintiff Terraine Abdullah is a natural adult person and a resident of Pennsylvania. Ms. Abdullah is the parent and natural guardian of H.S., a minor. Ms. Abdullah's address is 335 Passmore Street, Philadelphia, Pennsylvania 19111.

4. Defendant Mead Johnson Nutrition Company is a corporation, incorporated under the laws of the State of Delaware. Its principal place of business is Illinois. Defendant Mead Johnson & Company, LLC, is a limited liability company, organized under the laws of the State of Delaware. Its citizenship is that of its sole member, Mead Johnson Nutrition Company. Defendants Mead Johnson Nutrition Company and Mead Johnson & Company, LLC, (together, "Mead") are manufacturers of cow's milk-based infant feeding products and market many of these products under the "Enfamil" brand name.

5. Defendant Abbott Laboratories ("Abbott") is a corporation, incorporated under the laws of the State of Illinois. Its principal place of business is in Illinois. Abbott is a manufacturer of cow's milk-based infant feeding products and markets many of its products under the "Similac" brand name.

6. Defendant The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital is a non-profit corporation incorporated and registered to do business under the laws of the Commonwealth of Pennsylvania. Its principal place of business is Philadelphia, Pennsylvania. Pennsylvania Hospital is a registered name of The Pennsylvania Hospital of the University of Pennsylvania Health System. The sole member of The Pennsylvania Hospital of the University of Pennsylvania Health System is The Trustees of the University of Pennsylvania.

7. Defendant The Trustees of the University of Pennsylvania d/b/a Penn Medicine is a non-profit corporation registered to do business in the Commonwealth of Pennsylvania. Its principal place of business is Philadelphia, Pennsylvania. Penn Medicine is a registered name of The Trustees of the University of Pennsylvania.

III. JURISDICTION AND VENUE

8. This Court has jurisdiction in this matter pursuant to 42 Pa. C.S.A. § 931. Defendants conduct authorized business in the Commonwealth of Pennsylvania. They have sufficient minimum contacts with and purposefully avail themselves of the markets of this Commonwealth. This suit arises out of Defendants' forum-related activities, such that the Court of Common Pleas of Philadelphia County's exercise of jurisdiction would be consistent with traditional notions of fair play and substantial justice.

9. Venue is proper in the Court of Common Pleas of Philadelphia County pursuant to Rules 1006(b), 1006(c)(1), and 2179(a) of the Pennsylvania Rules of Civil Procedure because Defendants are corporations or similar entities that regularly conduct business in Philadelphia County, which is also the county where Plaintiff's causes of action arose, and the county where the occurrences took place out of which Plaintiff's causes of action arose.

10. This action is not subject to the Compulsory Arbitration Program of the Court of Common Pleas of Philadelphia County because the amount in controversy, excluding interest and costs, is in excess of $50,000.

IV. FACTUAL ALLEGATIONS

H.S.'s NEC Diagnosis

11. H.S. was born prematurely at Pennsylvania Hospital in Philadelphia, Pennsylvania on September 12, 2006.

12. Upon information and belief H.S. was fed Similac and/or Enfamil cow's milk-based products by staff at Pennsylvania Hospital from shortly after her birth.

13. Upon information and belief shortly after H.S. first ingested the Defendant Manufacturers' products, she developed NEC.

14. H.S. was forced to undergo surgery and has continued to suffer long term health effects.

Cow's Milk-Based Feeding Products Are Known to Cause NEC

15. NEC is a devastating disease that is the most frequent and lethal gastrointestinal disorder affecting preterm infants. NEC develops when harmful bacteria breach the walls of the intestine, causing portions of the intestine to become inflamed and often to die. Once NEC develops, the condition can progress rapidly from mild feeding intolerance to systemic and fatal sepsis. Up to 30 percent of NEC-diagnosed infants die from the disease.

16. Preterm and low-birth-weight infants are especially susceptible to NEC because of their underdeveloped digestive systems. Extensive scientific research, including numerous randomized controlled trials, has confirmed that cow's milk-based feeding products cause NEC in preterm and low-birth-weight infants, which in turn may lead to other medical complications, surgeries, long-term health problems, and death.

17. For example, in one randomized, multicenter study of 926 preterm infants, NEC was six to ten times more common in exclusively cow's milk formula-fed babies than in exclusively breast milk-fed babies and three times more common in babies who received a combination of formula and breast milk. For babies born at more than 30 weeks gestation, NEC was 20 times more common in those only fed cow's milk formula than in those fed breast milk.

18. Another randomized controlled trial showed that preterm babies fed an exclusive breast milk-based diet were 90% less likely to develop surgical NEC (NEC that requires surgical treatment), compared to preterm babies fed a diet that included some cow's milk-based products.

19. Yet another study that analyzed the data from a 12-center randomized trial concluded that fortification of breast milk with a cow's milk-based fortifier resulted in a 4.2-fold increased risk of NEC and a 5.1-fold increased risk of surgical NEC or death, compared to fortification with a breast milk-based fortifier.

20. A Surgeon General report, The Surgeon General's Call to Action to Support Breastfeeding, warns that, "for vulnerable premature infants, formula feeding is associated with higher rates of necrotizing enterocolitis." The report also states that premature infants who are not breastfed are 138% more likely to develop NEC.

21. The American Academy of Pediatrics, "an organization of 67,000 pediatricians committed to the optimal physical, mental, and social health and well-being for all infants, children, adolescents, and young adults," has advised that all premature infants should be fed either their mother's milk or, if their mother's milk is unavailable, pasteurized human donor milk. This recommendation is based on the "potent benefits of human milk," including "lower rates of . . . NEC."

22. A multicenter, randomized, controlled trial found that premature and low-birth-weight infants fed an exclusive breast milk-based diet suffered NEC only 3% of the time while premature and low-birth-weight infants receiving cow's milk-based formula suffered NEC 21% of the time.

23. Another study conducted a randomized comparison of extremely preterm infants who were given either (a) a diet of breast milk fortified with a breast milk-based fortifier or (b) a diet containing variable amounts of cow's milk-based products. The babies given exclusively breast milk products suffered NEC 5% of the time. The babies given cow's milk products suffered NEC 17% of the time.

Safer, Nutritionally Superior Alternatives To Cow's Milk-Based Products Exist

24. A range of options are available that allow preterm and low-birth-weight infants to be fed exclusively human milk-based nutrition. For example, in addition to the mother's own milk, an established network delivers pasteurized donor breast milk to hospitals nationwide. Moreover, hospitals have access to shelf-stable formula and fortifiers derived from pasteurized breast milk.

25. A diet based exclusively on breast milk and breast milk fortifiers provides all the nutrition necessary to support premature and low-birth-weight infants without the elevated risk of NEC associated with cow's milk-based products. For example, in a study analyzing preterm infants who were fed an exclusive breast milk-based diet until they reached 34 weeks, all 104 infants exceeded standard growth targets and met length and head-circumference growth targets, demonstrating that infants can achieve and mostly exceed targeted growth standards when receiving an exclusive breast milk-based diet. This is particularly true given the ability of breast milk-based fortifiers to provide the additional nutritional supplements necessary for adequate growth while receiving the protective benefits of a breast milk diet.

26. The Defendant Manufacturers' products not only pose a threat to infants' health, but also displace the breast milk they could otherwise receive. This displacement only increases infants' vulnerability to NEC, as studies show that breast milk protects against the disease. For example, a study analyzing 1,587 infants across multiple institutions concluded that an exclusive breast milk-based diet is associated with significant benefits for extremely premature infants and that it produced no feeding-related adverse outcomes.

27. For the above reasons, experts acknowledge that breast milk is the best source of nutrition for preterm infants and those at risk for NEC. Breast milk-based nutrition nourishes infants while creating a significantly lower risk of NEC.

28. At the time the Injured Infant was fed the Defendant Manufacturers' products, the science clearly demonstrated to Defendants that these products cause NEC and greatly increase the likelihood that a baby will develop NEC, leading to severe injury and often death.

29. Despite the scientific consensus that the Defendant Manufacturers' cow's milk-based products present a dire threat to the health and development of preterm infants, the Defendant Manufacturers have made no changes to their products or the products' packaging, guidelines, instructions, or warnings. Instead, they have continued to sell their unreasonably dangerous products. In addition, they incentivize hospitals that know the risks to use their products by providing them to the hospital for free or at a significant discount, in order that vulnerable infants and their families will become accustomed to using their products before discharge.

The Defendant Manufacturers' False And Misleading Marketing Regarding Cow's Milk-Based Infant Products

30. Abbott and Mead have aggressively marketed their cow's milk-based products as medically endorsed and nutritionally equivalent alternatives to breast milk, including prior to the Injured Infant's birth.

31. Abbott's and Mead's marketing approach includes targeting the parents of preterm infants while they are still in the hospital with messages that the Defendant Manufacturers' cow's milk formulas and fortifiers are necessary for the growth and development of their vulnerable children. Often these tactics implicitly discourage mothers from breastfeeding, which reduces the mother's supply of breast milk. None of the Defendant Manufacturers' marketing materials, including their promotional websites, reference the science showing how significantly their products increase the risk of NEC.

32. Numerous studies have shown the detrimental impact of formula advertising on the rates of initiation and continuation of breastfeeding, including studies that show that as "hand feeding" (non-breastfeeding) advertisements increase, reported breastfeeding rates decrease in the following year.

33. Undoubtedly aware of the impact of their advertising, the Defendant Manufacturers, along with other formula manufacturers, are willing to spend massive sums to disseminate their message, with one study estimating that formula manufacturers collectively spent $4.48 billion on marketing and promotion in 2014 alone.

34. Recognizing the abuse and dangers of infant formula marketing, in 1981, the World Health Assembly—the decision-making body of the World Health Organization—developed the International Code of Marketing of Breast-milk Substitutes ("the Code"), which required companies to acknowledge the superiority of breast milk, the negative effect on breastfeeding of introducing partial bottle-feeding, and the difficulty of reversing the decision not to breastfeed. The Code also forbade advertising or other forms of promotion of formula to the general public, as well as providing sample products to mothers or members of their families.

35. While Abbott and Mead acknowledge the Code on their websites and claim to support the effort to encourage mothers to breastfeed for as long as possible, this is little more than lip service. Instead, the Defendant Manufacturers' aggressive marketing exploits new parents' darkest fears—that the nutrition they are supplying to their child will not provide the best chance of survival—while wholly failing to warn that their products come with a significantly increased risk of NEC.

36. For example, Abbott's website, on a paged titled "Infant Formula Marketing," states: "We agree with the World Health Organization that breastfeeding provides the best nutrition for babies, and we support its goal to increase breastfeeding. We also recognize that for infants who aren't breastfed—for medical reasons or otherwise—infant formula is the only appropriate, safe alternative to meet babies' nutritional needs." This statement ignores the existence of donor milk, as well as human milk-based formula.

37. Abbott markets and sells multiple products specifically targeting preterm and low-birth-weight infants, including Liquid Protein Fortifier, Similac NeoSure, Similac Human Milk Fortifiers, Similac Special Care 20, Similac Special Care 24, Similac Special Care 24 High Protein, and Similac Special Care 30. In advertising these products, Abbott emphasizes the products' purported ability to assist underdeveloped babies in reaching their growth targets. For example, on the since-edited webpage regarding Similac NeoSure, Abbott noted: "Your premature baby didn't get her full 9 months in the womb, so her body is working hard to catch up. During her first full year, feed her Similac NeoSure, a nutrient-enriched formula for babies who were born prematurely, and help support her development." Yet, no mention was made of the accompanying significantly increased risk of NEC. At some point, the website was edited to remove this statement. However, upon information and belief, the statement remained on the website until at least December 2020.

38. Mead markets and sells multiple products specifically targeting premature infants, including Enfamil NeuroPro EnfaCare Infant Formula, Enfamil Premature Infant Formula 24 Cal High Protein, Enfamil Premature Infant Formula 30 Cal with Iron, Enfamil Premature Infant Formula 24 Cal with Iron, Enfamil Premature Infant Formula 20 Cal with Iron, Enfamil 24 Cal Infant Formula, and Enfamil Human Milk Fortifier (acidified liquid and powder). In advertising these products, Mead emphasizes the purported similarities between its formula and breast milk, while failing to include any information about the nutritional deficits and dangers that accompany formula use. For example, the since-edited webpage for Enfamil Enfacare stated: "Premature babies fed Enfamil® formulas during the first year have achieved catch-up growth similar to that of full term, breastfed infants" and noted that Enfamil formulas include "expert-recommended levels of DHA and ARA (important fatty acids found naturally in breast milk) to support brain and eye development."

39. One Enfamil advertisement, introducing a new product line called Enfamil NeuroPro, is entirely focused on favorably comparing Enfamil's formula to breast milk, without any mention of the product's extreme risks. Indeed, the terms "human milk" and "breast milk" are used 13 times in the advertisement, including in such statements as "for decades human milk has inspired the advancements in Enfamil formulas and now through extensive global research, we are taking an even closer look at human milk" and "only Enfamil NeuroPro has a fat blend of MFGM and DHA previously found only in breast milk." The webpage for the product has made similar manipulative claims, stating "Enfamil is backed by decades of breast milk research and multiple clinical studies" and it claims that "to create our best formulas, we collaborated on some of the most extensive breast milk studies to date[.]"

40. Formula manufacturers have long used their relationships with hospitals and the discharge process to encourage parents to substitute formula for breast milk. They offer free or reduced-cost formula to hospitals for use with infants before discharge. And they offer free formula, coupons, and even entire gift baskets to parents before their infants' discharge from the NICU or hospital.

41. Through this early targeting, the Defendant Manufacturers create brand loyalty under the guise of a "medical blessing," in hopes that new parents continue to use formula after they leave the hospital, resulting in increased expense for parents, significantly increased risk for babies, and increased profit for the Defendant Manufacturers. The Defendant Manufacturers' giveaways and gift baskets send confusing signals to mothers who are simultaneously being encouraged to breastfeed by their healthcare professionals, and they have been shown to negatively impact breastfeeding rates.

42. Further, when the Defendant Manufacturers recognized a shift in the medical community towards an exclusive breast milk-based diet for premature infants, Abbott developed a product called "Similac Human Milk Fortifier," and Mead developed "Enfamil Human Milk Fortifier." These names are misleading in that they suggest that the products are derived from breast milk, when, in fact, they are cow's milk-based products. One study, for example, found that only 8.8 percent of parents surveyed in the NICU interpreted "human milk fortifier" as potentially meaning a cow's milk-based product. The packaging appears as:

43. The Defendant Manufacturers have designed powerful misleading marketing campaigns to deceive parents into believing that: (1) cow's milk-based products are safe, including for preterm infants; (2) cow's milk-based products are equal, or even superior, substitutes to breast milk; (3) cow's milk-based products are necessary for proper growth and development of preterm infants; and (4) physicians consider the Defendant Manufacturers' cow's milk-based products to be a first choice. This marketing scheme is employed despite all Defendants knowing of and failing to warn of the extreme risk of NEC and death that cow's milk-based products pose to preterm infants like the Injured Infant.

The Defendant Manufacturers' Inadequate Warnings

44. Although Mead promotes an aggressive marketing campaign designed to convince parents that its cow's milk-based products are safe and necessary for the growth of a premature infant, the product is in fact extremely dangerous for premature infants. Enfamil products significantly increase the chances of a premature infant developing potentially fatal NEC.

45. The Enfamil products Mead markets specifically for premature infants are commercially available at retail locations and online. No prescription is necessary.

46. Despite knowing of the risk of NEC, the packaging of Mead's products does not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with Mead's products, or of the magnitude of this increased risk. Mead likewise did not provide instructions or guidance for how to avoid NEC.

47. Mead cites no medical literature or research to guide the use of its products.

48. Despite knowing of the risk of NEC, Mead did not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with its products, or of the magnitude of this increased risk. Mead likewise did not provide instructions or guidance for how to avoid NEC.

49. Mead deceived the public, parents, physicians, other medical professionals, and medical staff into believing that Enfamil products were a safe and necessary alternative, supplement and/or substitute to breast milk.

50. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Mead failed to require or recommend that medical professionals inform parents of the significant risk of NEC or to require that parental consent be obtained prior to the products being fed to their babies.

51. Like Mead, Abbott promotes an aggressive marketing campaign designed to make parents believe that its products are safe and necessary for the growth of premature infants, despite the products in fact being extremely dangerous for premature infants. Abbott's products significantly increase the chances of a premature infant getting potentially fatal NEC.

52. The products Abbott markets specifically for premature infants are available at retail locations and online. No prescription is necessary.

53. Despite knowing of the risk of NEC, Abbott did not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with its products, or of the magnitude of this increased risk. Abbott likewise did not provide instructions or guidance for how to avoid NEC.

54. Abbott deceived the public, parents, physicians, other medical professionals, and medical staff into believing that its products were a safe and necessary alternative, supplement and/or substitute to breast milk.

55. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Abbott failed to require or recommend that medical professionals inform parents of the significant risk of NEC or to require that parental consent be obtained prior to the products being fed to their babies.

Penn Medicine's Failure to Warn

56. On information and belief, Penn Medicine, which operates Pennsylvania Hospital, was aware of the significantly increased risk of NEC and death associated with providing Abbott's and Mead's cow's milk-based products to its premature infant patients. It knew or should have known that feeding these cow's milk-based products can cause NEC in premature infants who otherwise would not have developed this devastating condition. However, instead of warning of those

dangers, or supplying breast milk-based feeding products to preterm infants like the Injured Infant, Penn Medicine has continued to source, distribute, and supply the Defendant Manufacturers' products in its hospitals without any adequate warning.

57. To that end, Penn Medicine has participated in studies designed to increase the use of donor milk while, at the same time, reducing formula feeding in neonates. The University of Pennsylvania School of Nursing, an affiliate of Penn Medicine, has conducted extensive research into the risks associated with feeding formula to premature infants. It recently partnered with the National Institute of Nursing Research to publish clinical determinations based on its experience "changing hospital systems and influencing policy," and its findings were unequivocal:

> This is what we know about the science of human milk: it reduces the risk of necrotizing enterocolitis, reduces the risk of infection, [and] creates greater enteral feed tolerance and more rapid weaning from intravenous nutrition. . . .

Other Penn Medicine research has similarly concluded that "[h]uman milk decreases the incidence and severity of . . . necrotizing enterocolitis (NEC)."

58. Penn Medicine also purports to adhere to the tenets of the "Baby Friendly Hospital Initiative," which seeks to increase rates of breastfeeding initiation, exclusivity, and diet duration. The "Baby Friendly Hospital Initiative" specifically targets a reduction in the rates of NEC in preterm infants by encouraging implementation of exclusive breast milk diets among new mothers. Although Pennsylvania Hospital has maintained its "Baby Friendly" designation for years, it has not eliminated or restricted the use of formula or fortifier for preterm infants in its hospitals.

59. Finally, medical providers and staff at Penn Medicine have acknowledged the risks associated with providing the Defendant Manufacturers' cow's milk-based products to premature infant patients instead of breast milk-based nutrition. In an internal newsletter from 2012 touting donor milk programs, Penn Medicine acknowledged the benefits of a human milk-based diet, quoting a staff lactation consultant:

> Donor milk is not inexpensive. It costs about $4.25 per ounce, but the return on investment is huge. "Preemies given mother's milk get discharged three to four days sooner and also have a six to 10 times lower risk of getting a gastrointestinal complication called necrotizing enterocolitis," Carpenter said, adding that the infection can cost up to $250,000 to treat. The average cost to provide a preemie with donor milk: $125.

60. These statements demonstrate that Penn Medicine knew or should have known of the high increased risk of NEC for premature infants posed by the Defendant Manufacturers' products.

61. Although Penn Medicine knew or should have known of the serious danger of the Defendant Manufacturers' products, it has continued to purchase, supply, and distribute these products to preterm infants without providing full and adequate warnings of the attendant risks to parents, healthcare professionals, and other medical staff at its relevant facilities. As a result, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products at Pennsylvania Hospital, causing their injuries. This occurred even though hospitals across the country, including Pennsylvania Hospital, warn and obtain consent from parents before providing other safer forms of nutrition, such as donor breast milk.

62. Penn Medicine's failure to warn of the risks posed by the Defendant Manufacturers' products is entrenched (and compounded) by the financial benefits it accrues from its relationships with the Defendant Manufacturers. On information and belief, it has received the Defendant Manufacturers' cow's milk-based products for free or at a significant discount, and has granted their sales representatives access to its healthcare professionals and medical staff. These sales representatives have provided deceptive information that Penn Medicine reasonably knew or should have known would ultimately reach parents through those staff. This arrangement dovetails with the Defendant Manufacturers' own marketing strategy, which aims to "sell and service" healthcare professionals and medical staff as a means of converting them into "extra salespersons."

Safer Alternative Designs

63. The Defendant Manufacturers' cow's milk-based products made specifically for premature infants are unreasonably unsafe for those infants. The Defendant Manufacturers could have used pasteurized breast milk instead of cow's milk in their products, which would have produced a safer product.

64. Prolacta Bioscience manufactures and sells breast milk-based feeding products, specifically designed for preterm infants, which contain no cow's milk. This alternative design provides all the necessary nutrition for growth and development that cow's milk-based products provide, without the same unreasonably dangerous and deadly effects.

65. On information and belief, Abbott and Mead were aware of the significantly increased risk of NEC and death associated with their cow's milk-based products, and instead of warning of the dangers, or removing them altogether, Abbott and Mead have continued to use cow's milk as the foundation of their products.

CAUSES OF ACTION

COUNT I: STRICT LIABILITY FOR DESIGN DEFECT
(Against Abbott and Mead)

66. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

67. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to manufacture, sell, and distribute their products in a manner that was not unreasonably dangerous.

68. Abbott and Mead also owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to manufacture, sell, and distribute their products in a manner that was merchantable and reasonably suited for their intended use.

69. Abbott and Mead knew that their products would be used to feed premature infants like the Injured Infant and knew (or reasonably should have known) that use of their cow's milk-based products significantly increased the risk of NEC, serious injury, and death, and that such use was therefore unreasonably dangerous to premature infants, not reasonably suited for the use intended, not merchantable, and had risks that exceeded a reasonable buyer's expectations. Nonetheless, they continued to sell and market their defective products as appropriate for premature infants.

70. The Injured Infant ingested Abbott and/or Mead's unreasonably dangerous cow's milk-based products. The risks of feeding those products to the Injured Infant outweighed the benefits. An ordinary consumer would not expect those products to carry a significant risk of serious injury and death from NEC.

71. Abbott and Mead knew (or reasonably should have known) that breast milk-based nutrition did not carry the same risks of NEC, serious injury, and death that their products do.

72. Abbott's and Mead's products contained cow's milk at the time they left the manufacturing facility.

73. Abbott and Mead did not develop a human-milk based product that was safer for premature infants and did not reformulate their products to reduce the risk of NEC, serious injury, and death, even though doing so was economically and technologically feasible and even though pasteurized breast milk was an available alternative.

74. Abbott's and/or Mead's products were fed to the Injured Infant, which caused and/or increased the risk of their NEC and injuries.

75. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

a. For compensatory damages in an amount to be proven at trial and in excess of $50,000 and this Court's arbitrational limit;

b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;

c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

d. For punitive damages in excess of $50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;

e. For interest as permitted by law;

f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and

g. For such other and further relief as the Court deems proper.

COUNT II: STRICT LIABILITY FOR FAILURE TO WARN
(Against Abbott and Mead)

76. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

77. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide adequate warnings or instructions about the dangers and risks associated with the use of

their products with preterm infants, specifically including but not limited to the risk of NEC, serious injury, and death.

78. Abbott's and Mead's duty to warn is part of their general duty to design, manufacture, and sell their infant products in a manner that is reasonably safe for their foreseeable uses. By designing their products with cow's milk-based ingredients, Abbott and Mead undertook a duty to warn of the unreasonable risk of harm posed by those ingredients, specifically including the significantly increased risk of NEC, severe injury, and death. The failure to warn makes the products at issue in this litigation unreasonably dangerous.

79. Specifically, Abbott and Mead breached their duty to warn of the foreseeable risks of the infant products at issue in this litigation because they knew or should have known that their cow's milk-based premature infant products would be fed to premature infants like the Injured Infant, and that their products might cause the Injured Infant to develop NEC, severe injury, or death, yet they failed to provide adequate warnings of those risks. Among other risks, the Defendant Manufacturers:

a. Failed to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death for the Injured Infant; and/or

b. Failed to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or

c. Inserted warnings and instructions on their products that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or

d. Failed to insert a large and prominent "black box"-type warning that their cow's milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infant; and/or

e. Failed to disclose well-researched and well-established studies that linked cow's milk-based products to NEC and death in premature infants; and/or

f. Failed to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risks; and/or

g. Failed to provide a warning in a method reasonably calculated or expected to reach the parents of newborns, like the Plaintiff Parent; and/or

h. Failed to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products.

80. Abbott's and Mead's products contained cow's milk at the time they left the manufacturing facility.

81. As a direct and proximate result of the inadequacy of the warnings and the pervasive marketing campaigns suggesting the safety and necessity of the Defendant Manufacturers' products, the Injured Infant were fed cow's milk-based products, which caused and/or increased risk of their developing NEC.

82. The unwarned-of risks are not of a kind that an ordinary consumer would expect. Had physicians and medical staff known of the extreme risk associated with feeding premature infants cow's milk-based formula, they would not have fed the Injured Infant those products. Had the

Plaintiff Parent known of the significant risks of feeding the Injured Infant cow's milk-based formula, they would not have allowed such products to be fed to the Injured Infant.

83. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

a. For compensatory damages in an amount to be proven at trial and in excess of $50,000 and this Court's arbitrational limit;

b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;

c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

d. For punitive damages in excess of $50,000 and this Court's arbitrational limit resulting from the Defendants Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;

e. For interest as permitted by law;

f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and

g. For such other and further relief as the Court deems proper.

COUNT III: NEGLIGENCE
(Against Abbott and Mead)

84. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

85. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to exercise reasonable care to design, test, manufacture, inspect, and distribute a product free of unreasonable risk of harm to users, when such products are used in their intended manner and for their intended purpose.

86. At all times relevant to this action, the Injured Infant's healthcare professionals and medical staff used the products at issue in their intended manner and for their intended purpose.

87. Abbott and Mead, directly or indirectly, negligently, and/or defectively made, created, manufactured, designed, assembled, tested, marketed, sold, and/or distributed the cow's milk-based infant products at issue in this litigation and thereby breached their duty to the general public and the Plaintiff Parent.

88. Specifically, although Abbott and Mead knew or reasonably should have known at the time of production that their cow's milk-based infant products significantly increased the risk of NEC, serious injury, and death, they failed to act in a reasonably prudent manner and breached their duty by:

a. Failing to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death for the Injured Infant; and/or

b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or

c. Inserting warnings and instructions that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or

d. Failing to insert a large and prominent "black box"-type warning that their cow's milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infants; and/or

e. Failing to provide well-researched and well-established studies that linked cow's milk-based products to NEC and death in premature infants; and/or

f. Failing to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risks; and/or

g. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns, like the Plaintiff Parent; and/or

h. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products.

89. In addition, although Abbott and Mead knew or reasonably should have known at the time of production that their cow's milk-based products significantly increased the risk of NEC, serious injury, and death, they failed to act in a reasonably prudent manner and breached their duty by failing to perform the necessary process of data collection, detection, assessment, monitoring, prevention, and reporting or disclosure of adverse outcomes in infants who ingest their products.

90. As a direct and proximate result of the Defendant Manufacturers' failure to act in a reasonably prudent manner and their breach of duty, the Injured Infant was fed cow's milk-based products, which caused and/or increased the risk of their developing NEC.

91. Had Abbott and Mead satisfied their duties to the consuming public in general, the Injured Infant would not have been exposed to their unreasonably dangerous cow's milk-based products.

92. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

a. For compensatory damages in an amount to be proven at trial and in excess of $50,000 and this Court's arbitrational limit;

b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;

c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

d. For punitive damages in excess of $50,000 and this Court's arbitrational limit resulting from the Defendants Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;

e. For interest as permitted by law;

f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and

g. For such other and further relief as the Court deems proper.

COUNT IV: INTENTIONAL MISREPRESENTATION
(Against Abbott and Mead)

93. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

94. At all times relevant to this action, the Injured Infant consumed the Defendant Manufacturers' products in their intended manner and for their intended purpose.

95. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide truthful, accurate, fulsome information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

96. Abbott and Mead breached their duty through misrepresentations made to consumers, physicians, and medical staff in their advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable and intended recipients of this information.

97. Specifically, upon information and belief, Abbott and Mead made the following false statements of material fact on an ongoing and repeated basis and prior to the time the Injured Infant was fed their products:

a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or

b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or

c. That their products have no serious side effects, when they knew or should have known the contrary to be true; and/or

d. That cow's milk-based products were safe for premature infants; and/or

e. That cow's milk-based products were necessary for optimum growth; and/or

f. That cow's milk-based products were similar or equivalent to breast milk; and/or

g. That their products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or

h. That their products were based on up-to-date science, which made them safe for premature infants; and/or

i. Omitting the material fact that their products significantly increased the risk of NEC in premature infants.

98. Abbott and Mead knew or reasonably should have known those misrepresentations to be false.

99. The Defendant Manufacturers' misrepresentations were intended to, and in fact did, induce physicians and medical staff, including the Injured Infant's physicians and medical staff, to provide their infant products to babies, including the Injured Infant.

100. The Plaintiff Parent was not aware that these misrepresentations were false and justifiably relied on them. The Defendant Manufacturers' misrepresentations induced the Plaintiff Parent to allow their children to be fed Abbott's and Mead's infant products, in reliance on all the messaging they received about formula feeding, including, directly or indirectly, the Defendant Manufacturers' messaging. Had Abbott and Mead not committed these intentional

misrepresentations, the Injured Infant would not have been exposed to the Defendant Manufacturers' unreasonably dangerous cow's milk-based products.

101. As a direct and proximate result, Abbott's and Mead's products were fed to the Injured Infant, which caused and/or increased risk of their developing NEC and subsequent injuries.

102. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

a. For compensatory damages in an amount to be proven at trial and in excess of $50,000 and this Court's arbitrational limit;

b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;

c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

d. For punitive damages in excess of $50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;

e. For interest as permitted by law;

f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and

g. For such other and further relief as the Court deems proper.

COUNT V: NEGLIGENT MISREPRESENTATION
(Against Abbott and Mead)

103. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

104. At all times relevant to this action, the Injured Infant consumed the products at issue in their intended manner and for their intended purpose.

105. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide truthful, accurate, and complete information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

106. In the course of their business, Abbott and Mead breached their duty through misrepresentations made to consumers, physicians, and medical staff in their advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable recipients of this information.

107. Specifically, upon information and belief, Abbott and Mead made the following false statements of material fact on an ongoing and repeated basis and prior to the time the Injured Infant was fed their products:

a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or

b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or

c. That their products have no serious side effects, when they knew or should have known the contrary to be true; and/or

d. That cow's milk-based products were safe for premature infants; and/or

e. That cow's milk-based products were necessary for optimum growth; and/or

f. That cow's milk-based products were similar or equivalent to breast milk; and/or

g. That their products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or

h. That their products were based on up-to-date science, which made them safe for premature infants; and/or

i. Omitting the material fact that their products significantly increased the risk of NEC in premature infants.

108. Abbott and Mead were negligent or careless in not determining those representations to be false.

109. The Defendant Manufacturers' misrepresentations were intended to and did in fact induce physicians and medical staff, including the Injured Infant's physicians and medical staff, to provide their products to babies, including the Injured Infant.

110. The Defendant Manufacturers' misrepresentations induced, and were intended to induce, the Plaintiff Parent to allow their child to be fed Abbott's and Mead's infant products, in justifiable reliance on all the messaging they received about formula feeding, including, directly or indirectly, the Defendant Manufacturers' messaging. Had Abbott and Mead not committed these negligent

misrepresentations, the Injured Infant would not have been exposed to their unreasonably dangerous cow's milk-based products.

111. As a direct and proximate result, Abbott's and Mead's products were fed to the Injured Infant, which caused and/or increased of their developing NEC and subsequent injuries.

112. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

a. For compensatory damages in an amount to be proven at trial and in excess of $50,000 and this Court's arbitrational limit;

b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;

c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

d. For punitive damages in excess of $50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;

e. For interest as permitted by law;

f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and

g. For such other and further relief as the Court deems proper.

COUNT VI: FAILURE TO WARN
(Against Penn Medicine and Pennsylvania Hospital)

113. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

114. Penn Medicine and Pennsylvania Hospital as purchaser, supplier, and/or distributor of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to purchase, supply, and distribute products that were free of unreasonable risk of harm when used in their intended manner and for their intended purpose, and/or to formulate, adopt, and enforce adequate rules and policies for the same.

115. At all times relevant to this action, the Injured Infant used the cow's milk-based products purchased, supplied, and/or distributed by Penn Medicine and Pennsylvania Hospital in their intended manner and for their intended purpose.

116. Penn Medicine and Pennsylvania Hospital employed or contracted with the healthcare professionals and medical staff at Pennsylvania Hospital, managing these individuals during their treatment of the Injured Infant.

117. Penn Medicine and Pennsylvania Hospital negligently and recklessly supplied and distributed the Defendant Manufacturers' milk-based infant feeding products to these healthcare professionals and medical staff for use on premature infants, including the Injured Infant.

118. Moreover, at all relevant times, Penn Medicine and Pennsylvania Hospital knowingly authorized the Defendant Manufacturers' sales representatives to market, advertise, distribute, and/or sell their products at Pennsylvania Hospital. The Defendant Manufacturers' sales representatives were encouraged to interact with Pennsylvania Hospital's healthcare professionals and medical staff. These interactions provided the Defendant Manufacturers' sales representatives

an opportunity to co-opt Pennsylvania Hospital's healthcare professionals and medical staff into assisting with the marketing, distribution, and/or sale of the Defendant Manufacturers' unreasonably dangerous products to consumers, such as the Plaintiff Parent.

119. Penn Medicine and Pennsylvania also knowingly allowed the Defendant Manufacturers' sales representatives to routinely misrepresent the risks and benefits of Defendants' products to Pennsylvania Hospital's healthcare professionals and medical staff, including the misrepresentation that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

120. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known at the time that they acquired, distributed, and supplied the Defendant Manufacturers' cow's milk-based infant products that these products significantly increased the risk of NEC, serious injury, and death.

121. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, recklessly and breached its duty by:

a. Failing to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or

b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or

c. Failing to warn or instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or

d. Failing to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or

e. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns; and/or

f. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products; and/or

g. Failing to prevent the Defendant Manufacturers' sales representatives from misrepresenting to Pennsylvania Hospital's healthcare professionals and medical staff that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

122. Reasonable hospitals under the same or similar circumstances would have warned of the above risks, would have instructed their healthcare professionals and medical staff—as well as patients—on the safe use of the Defendant Manufacturers' products, and would have restricted the ability of the Defendant Manufacturers' sales representatives to market the Defendant Manufacturers' unreasonably dangerous products without adequate warning.

123. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that its medical professionals and the parents of premature infants, including the Plaintiff Parent, would not have realized the risks associated with feeding cow's milk-based formula to premature infants.

124. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to warn its medical providers and patients about the Defendant Manufacturers' unreasonably dangerous products, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

125. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to warn of the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

126. As a further direct and proximate result of Penn Medicine and Pennsylvania failure to warn of the Defendant Manufacturers' unreasonably dangerous products, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against Penn Medicine and Pennsylvania Hospital as follows:

a. For compensatory damages in an amount to be proven at trial and in excess of $50,000 and this Court's arbitrational limit;

b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of Penn Medicine's conduct;

c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

d. For punitive damages in excess of $50,000 and this Court's arbitrational limit resulting from Penn Medicine and Pennsylvania Hospital's oppressive, reckless, and/or malicious conduct, as permitted by law;

e. For interest as permitted by law;

f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and

g. For such other and further relief as the Court deems proper.

COUNT VII: CORPORATE LIABILITY OF HEALTH-CARE PROVIDER
(Against Penn Medicine and Pennsylvania Hospital)

127. Plaintiff incorporates by references each of the preceding paragraphs as if fully set forth herein.

128. At all relevant times, Penn Medicine and Pennsylvania Hospital owed a duty of care to the Injured Infant to ensure their safety and well-being while the Injured Infant was under the care of Pennsylvania Hospital staff. Specifically, Penn Medicine and Pennsylvania Hospital had a duty to the Injured Infant to formulate, adopt, and enforce adequate rules and policies to ensure quality care for the Injured Infant. Further, Penn Medicine and Pennsylvania Hospital owed a duty to the Injured Infant to oversee its healthcare professionals and medical staff that provided patient care to the Injured Infant.

129. Penn Medicine and Pennsylvania Hospital owed a duty to its patients, and the Injured Infant in particular, to formulate, adopt, and enforce adequate rules and policies for the purchase, supply, distribution, and use of products that were free of unreasonable risk of harm when used in their intended manner and for their intended purpose and ensured quality care for the Injured Infant.

130. At all times relevant to this action, the Injured Infant used the cow's milk-based products purchased, supplied, and/or distributed by Penn Medicine and Pennsylvania Hospital in their intended manner and for their intended purpose.

131. Moreover, at all relevant times, Penn Medicine and Pennsylvania Hospital knowingly authorized the Defendant Manufacturers' sales representatives to market, advertise, distribute,

and/or sell their products at Pennsylvania Hospital. The Defendant Manufacturers' sales representatives were encouraged to interact with Pennsylvania Hospital's healthcare professionals and medical staff. These interactions provided the Defendant Manufacturers' sales representatives an opportunity to co-opt Pennsylvania Hospital's healthcare professionals and medical staff into assisting with the marketing, distribution, and/or sale of the Defendant Manufacturers' unreasonably dangerous products.

132. Penn Medicine and Pennsylvania Hospital also knowingly allowed the Defendant Manufacturers' sales representatives to routinely misrepresent the risks and benefits of Defendants' products to Pennsylvania Hospital's healthcare professionals and medical staff, including the misrepresentation that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

133. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known at the time that it formulated, adopted, and enforced its rules for the acquisition, distribution, and supply of the Defendant Manufacturers' cow's milk-based infant products, including the access afforded the Defendant Manufacturer's sales representatives, that these products significantly increased the risk of NEC, serious injury, and death for premature infants.

134. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that its medical professionals and the parents of premature infants, including the Plaintiff Parent, would not have realized the risks associated with feeding cow's milk-based formula to premature infants.

135. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, recklessly and breached its duty by:

a. Failing to formulate, adopt, and enforce adequate rules and policies that would have restricted the use of cow's milk-based products for feeding premature babies; and/or

b. Failing to formulate, adopt, and enforce adequate rules and policies that warned the Plaintiff Parent that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in premature babies, like the Injured Infant; and/or

c. Failing to formulate, adopt, and enforce adequate rules and policies that warned its healthcare professionals and medical staff that cow's milk-based products are unsafe and/or contraindicated for premature babies like the Injured Infant; and/or

d. Failing to formulate, adopt, and enforce adequate rules and policies to instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or

e. Failing to formulate, adopt, and enforce adequate rules and policies to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or

f. Failing to formulate, adopt, and enforce adequate rules and policies to ensure a warning in a method reasonably calculated/expected to reach the parents of newborns, like the Plaintiff Parent; and/or

g. Failing to formulate, adopt, and enforce adequate rules and policies to prevent the Defendant Manufacturers' sales representative from misrepresenting to

Pennsylvania Hospital's healthcare professionals and medical staff that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants; and/or

h. Failing to establish a donor milk program that was sufficient to meet the needs of the premature babies, like the Injured Infant.

136. A reasonable hospital under the same or similar circumstances would have formulated, adopted, and enforced adequate policies, and rules to restrict the feeding of cow's milk-based products to premature babies, including developing an adequate donor milk program, instructing its healthcare professionals and medical staff on the safe use of Defendants Manufacturers' cow's milk-based products, and restricting the marketing of the Defendant Manufacturers' unreasonably dangerous products to its healthcare professionals, medical staff, and parents of premature infants under its care.

137. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to formulate, adopt, and enforce adequate rules and policies to ensure the quality care of its patients, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

138. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital failure to formulate and enforce adequate policies and rules related to the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

139. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital negligent and reckless conduct the Plaintiff Parent suffered significant emotional distress, loss of

income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

140. In the alternative, Penn Medicine and Pennsylvania Hospital owed a duty to its patients, and the Injured Infant in particular, to oversee the practicing healthcare professionals and medical staff that provided the products at issue to infants under Pennsylvania Hospital's care, including the Injured Infant.

141. Penn Medicine and Pennsylvania Hospital employed or contracted with the healthcare professionals and medical staff at Pennsylvania Hospital and was responsible for overseeing those individuals during their treatment of the Injured Infant.

142. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, recklessly and breached its duty by:

a. Failing to oversee its healthcare professionals and medical staff on their use of cow's milk-based products for feeding premature babies; and/or

b. Failing to warn or instruct its healthcare professionals and medical staff that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or

c. Failing to warn or instruct its healthcare professionals and medical staff that cow's milk-based products are unsafe and/or contraindicated for premature babies like the Injured Infant; and/or

d. Failing to oversee its healthcare professionals and medical staff to restrict their feeding of cow's milk-based products to premature babies; and/or

e. Failing to warn or instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice

about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or

f. Failing to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or

g. Failing to provide its healthcare professionals and medical staff with warnings about the dangers of the Defendants' Manufacturers products in a method reasonably calculated/expected to reach the parents of newborns; and/or

h. Failing to provide statistical evidence to its healthcare professionals and medical staff showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products; and/or

i. Failing to oversee its healthcare professionals and medical staff to ensure that the Defendant Manufacturers' sales representatives' misrepresentations that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants had not influenced the use and/or misuse of the Defendant Manufacturers' products.

143. A reasonable hospital under the same or similar circumstances would have warned of the above risks, would have instructed its healthcare professionals and medical staff on the safe use of the Defendant Manufacturers' products, and would have restricted the ability of the Defendant Manufacturers' sales representatives to market the Defendant Manufacturers' unreasonably dangerous products without adequate warning.

144. A reasonable hospital under the same or similar circumstances would have overseen and managed its healthcare professionals and medical staff to ensure that they received proper training and updating on the risks associated with feeding cow's milk-based formula to premature infants.

145. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to oversee its healthcare professionals and medical staff who provide patient care, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

146. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to oversee its healthcare professionals and medical staff on the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

147. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital's negligent and reckless conduct, , the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against Penn Medicine and Pennsylvania Hospital as follows:

a. For compensatory damages in an amount to be proven at trial and in excess of $50,000 and this Court's arbitrational limit;

b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of Penn Medicine and Pennsylvania Hospital's conduct;

c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

d. For punitive damages in excess of $50,000 and this Court's arbitrational limit resulting from Penn Medicine's oppressive, fraudulent, and/or malicious conduct, as permitted by law;

e. For interest as permitted by law;

f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and

g. For such other and further relief as the Court deems proper.

DEMAND FOR JURY TRIAL

148. Plaintiff hereby demands a jury trial for all claims triable.

Dated: March 24, 2022

Respectfully submitted,

ANAPOL WEISS

Tracy Finken
130 N. 18th Street, Suite 1600
Philadelphia, PA 19103
Phone: (215) 735-1130
Email: tfinken@anapolweiss.com

KELLER LENKNER LLC
Ashley Keller (*pro hac vice forthcoming*)
150 N. Riverside Plaza, Suite 4100
Chicago, Illinois 60606

Telephone: (312) 741-5220
Fax: (312) 971-3502
Email: ack@kellerlenkner.com

WALSH LAW PLLC
Alex Walsh (*pro hac vice forthcoming*)
1050 Connecticut Ave, NW, Suite 500
Washington, D.C. 20036
Telephone: (202) 780-4127
Fax: (202) 780-3678
Email: awalsh@alexwalshlaw.com

Attorneys for Plaintiffs

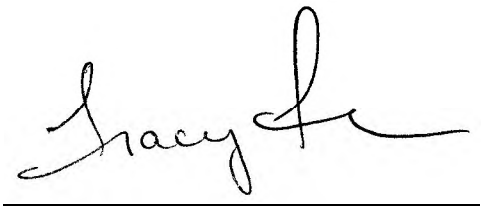
CERTIFICATE OF SERVICE

I hereby certify that on March 24, 2022, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF and that the foregoing document is being served on all counsel of record or parties registered to receive CM/ECF Electronic Filings.

Tracy Finken

VERIFICATION

I, the undersigned, Tracy Finken, verify that the statements made in this document are true and correct to the best of my knowledge, information, and belief. I understand that false statements herein are made subject to the penalties of 18 Pa. C.S. §4904, relating to unsworn falsification to authorities.



Date: March 24, 2022

Tracy Finken

EXHIBIT B

MEDICAL SCIENCE

Breast milk and neonatal necrotising enterocolitis

A. LUCAS T. J. COLE

In a prospective multicentre study on 926 preterm infants formally assigned to their early diet, necrotising enterocolitis developed in 51 (5·5%). Mortality was 26% in stringently confirmed cases. In exclusively formula-fed babies confirmed disease was 6–10 times more common than in those fed breast milk alone and 3 times more common than in those who received formula plus breast milk. Pasteurised donor milk seemed to be as protective as raw maternal milk. Among babies born at more than 30 weeks' gestation confirmed necrotising enterocolitis was rare in those whose diet included breast milk; it was 20 times more common in those fed formula only. Other risk factors included very low gestational age, respiratory disease, umbilical artery catheterisation, and polycythaemia. In formula-fed but not breast-milk-fed infants, delayed enteral feeding was associated with a lower frequency of necrotising enterocolitis. With the fall in the use of breast milk in British neonatal units, exclusive formula feeding could account for an estimated 500 extra cases of necrotising enterocolitis each year. About 100 of these infants would die.

Lancet 1990; **336**: 1519–23.

Introduction

Necrotising enterocolitis is the most common serious gastrointestinal disease seen in neonatal intensive care units, with a reported mortality in well-established cases of 20–40%.[1] The causes have been elusive. Prematurity or low birthweight are the most consistently reported associated factors,[2] but up to 10% of cases occur in term babies.[3] Some studies suggest a strong relation between necrotising enterocolitis and factors that could cause gut ischaemia or hypoxia;[4-6] others fail to find these associations.[1,2,7] An infective aetiology has been suggested by case clustering, the presence of a predominant organism in outbreaks, the effectiveness of standard infectious disease control methods in epidemics,[8,9] and the apparent prophylactic value of oral immunoglobulin.[10] Nevertheless, no single organism has proved to be the cause[11] and most of the microorganisms identified are present in normal gut flora. The importance of enteral feeding as a risk factor has been emphasised,[3,12-14] but 5–10% of cases occur in babies who have never been enterally fed.[1,3] Further suggested factors related to feeding include early initiation of enteral feeds,[14] rapid escalation of feed volumes,[13] and hyperosmolar feeding,[15,16] but others doubt their importance.[4,17] Several small studies and anecdotal observations[18-20] have suggested that breast milk is protective. This idea is supported by findings in a rat model that live milk leucocytes are prophylactic.[21,22] Nevertheless, necrotising enterocolitis can occur in infants fed exclusively on fresh, frozen, or pasteurised breast milk.[4,14,23]

It seems that no single aetiological factor explains necrotising enterocolitis and that the mucosal lesion can be provoked in several ways. An important question, however, is whether there are any important risk factors that can be avoided readily in clinical practice. Feeding policy is the factor most amenable to manipulation. In our prospective, randomised, multicentre study of dietary management in 926 infants,[24] we have re-explored the relation between early diet or feeding practice and the frequency of necrotising enterocolitis.

Subjects and methods

926 infants with birthweights below 1850 g (mean 1370 [SD 320] g; mean gestation 31 [3] weeks) were recruited in five centres, to test whether early diet, randomly assigned, affected short-term morbidity and long-term outcome. Necrotising enterocolitis was identified as a major short-term outcome response.

There were two parallel dietary studies. In three centres (study A) infants were randomly assigned to pasteurised banked donated breast milk or a nutrient-entriched preterm formula ('Osterprem', Farley Health Products Ltd, Nottingham, UK). The randomisation was stratified according to whether the mother provided breast milk for her own infant. Thus, donor milk and preterm formula could be compared as sole diets (in infants whose mothers did not provide their own milk) or as supplements to breast milk. In two further centres (study B) the same randomisation procedure was used to compare infants fed a standard "term" formula ('Ostermilk', Farley Health Products Ltd) or the preterm formula, again as sole diets or as supplements to mother's milk. When the trial diets (donor milk, term formula, or preterm formula) were used as a supplement to maternal breast milk, the median intake of mother's milk was 48% (interquartile range 10–86%) with no difference between diet groups. Randomisation is described elsewhere;[24] it took place within 48 h of birth, independently in each

ADDRESS: **University Department of Paediatrics and MRC Dunn Nutrition Unit, Cambridge, UK** (A. Lucas, MRCP, T. J. Cole, PhD). Correspondence to Dr A. Lucas, MRC Dunn Nutrition Unit, Downhams Lane, Milton Road, Cambridge CB4 1XJ, UK.

centre, and assignments were based on permuted blocks of variable length.

Detailed composition of the formulas is available from the manufacturers. Briefly, for each 100 ml the standard formula contained 1·45 g protein and 286 kJ (68 kcal), and the preterm formula 2·0 g protein and 336 kJ (80 kcal). The preterm formula was also enriched in sodium, calcium, phosphorus, copper, zinc, vitamins D, E, and K, water-soluble vitamins, carnitine, and taurine. The osmolality of both formulas was 300 mosmol/kg. Donor breast milk was pasteurised and frozen. Mother's milk was not pasteurised and was fed untreated or after a period of refrigeration or, occasionally, freezing.

Various classifications have been proposed for necrotising enterocolitis.[25,26] We have used the British Association for Perinatal Pediatrics classification based on features of the disease in 165 cases in 54 British centres.[26] Grade 1 cases had at least two of the following features: pneumatosis intestinalis on abdominal radiograph; abdominal distension or an abdominal radiograph showing gaseous distension or frothy appearance of bowel lumen (or both); blood in the stool; lethargy, hypotonia, or apnoeic episodes, or a combination of the three. Grade 2 cases had, as well as grade 1 features, one or more of: abdominal tenderness or rigidity; tissue (mucosa) in stool; abnormal bleeding with trauma; spontaneous bleeding; peripheral white blood cell count below 6×10^9/l at the time of illness; peripheral platelet count below 100×10^9/l at the time of illness; or an abdominal radiograph showing gas in the portal vein or free air in the abdomen. The cases were further divided into confirmed cases (with classic radiological features [pneumatosis intestinalis, gas in the portal venous system, or free air in the abdomen] or with necrotising enterocolitis established surgically or at necropsy) and unconfirmed cases.

The frequency of necrotising enterocolitis was examined among the randomised diet groups. In the main analysis, however, necrotising enterocolitis was examined in three non-randomised enteral feed groups—human milk only (donor or donor plus mother's milk), formula (term or preterm) as a supplement to mother's milk, and formula only. Extensive logistic regression analyses were used—to adjust for potential confounding factors in the comparison between non-randomised feed groups; to quantify other risk factors for necrotising enterocolitis; and to identify interactions between diet and non-dietary factors. For most analyses, data are presented for all cases of necrotising enterocolitis and for confirmed cases only.

Results

Clinical features of necrotising enterocolitis developed in 51 of the 926 infants studied, and the diagnosis was more stringently "confirmed" in 31 (table I). All the infants who required surgery or who died had grade 2 confirmed disease. Of the confirmed cases, 35% needed surgery, and necrotising enterocolitis was considered the principal cause of death in 26%. All infants in whom necrotising enterocolitis developed had received enteral feeds.

The clinical characteristics of the study population and the higher frequency of necrotising enterocolitis at low gestation and with respiratory disease are shown in table II.

The only formal randomised comparison of human milk and formula feeding on the incidence of necrotising enterocolitis was that of infants fed exclusively on donor breast milk or on preterm formula. Among the 86 infants exclusively fed on donor milk there were 3 (4%) cases (1 [1%] confirmed cases) and among the 76 fed exclusively on preterm formula there were 6 (8%) cases (4 [5%] confirmed); the odds ratios were 2·4 (95% CI 0·6–9·8) for all cases and 4·7 (0·5–43) for confirmed cases. However, the sample size was not large enough to detect a difference smaller than ten-fold in frequency of necrotising enterocolitis between these groups with adequate power. In study A as a whole there were 11 (43%) cases among the 253 infants who received donor milk alone or with maternal milk

TABLE I—OCCURRENCE AND OUTCOME OF NECROTISING ENTEROCOLITIS

—	No of babies *(% of total)*	No *(% of group)* who required surgery	No *(% of group)* who died
Grade 1			
Unconfirmed	16 *(1·7%)*	0	0
Confirmed	9 *(1·0%)*	0	0
Grade 2			
Unconfirmed	4 *(0·4%)*	0	0
Confirmed	22 *(2·4%)*	11 *(50%)*	8 *(36%)*
Total cases	51 *(5·5%)*	11 *(22%)*	8 *(16%)*
Confirmed cases	31 *(3·3%)*	11 *(35%)*	8 *(26%)*

(3 [1·2%] confirmed) and 12 (4·8%) cases among the 249 who received preterm formula as a sole diet or with maternal milk (9 [3·6%] confirmed). The odds ratios were 1·1 (0·5–2·6) for all cases and 3·1 (0·8–11·7) for confirmed cases; however, the 3-fold difference was not significant ($p = 0·07$). In study B the incidence of necrotising enterocolitis was similar in infants fed preterm or term formula either as sole diets (6/81 cases *vs* 11/79 cases) or as supplements to mother's milk (12/213 cases *vs* 16/211 cases).

The 253 subjects fed only human milk ranged from those fed exclusively pasteurised donor milk to those fed almost entirely raw maternal milk. More detailed data modelling (not shown here) confirmed the findings above, that the incidence of necrotising enterocolitis in this subgroup was not affected by the type of breast milk consumed.

Since the occurrence of necrotising enterocolitis was the same in infants fed on different types of breast milk and in infants fed on the two types of formula, we were able to divide the whole population into three large diet groups for comparison—formula only ($n = 236$), formula plus breast milk ($n = 437$), and human milk only ($n = 253$). The formula only group were at a significantly higher risk of necrotising enterocolitis than the other groups (table III). The odds ratio (95% CI) for the comparison of formula only and formula plus mother's milk was 3·0 (1·5–5·7; $p < 0·005$) for all cases and 3·0 (1·4–6·5; $p < 0·005$) for confirmed cases. For the comparison of formula only and breast milk only the odds ratios were 2·5 (1·2–5·2; $p < 0·02$) for all cases and 6·5 (1·9–22; $p < 0·001$) for confirmed cases.

This comparison might have been confounded by the fact that the infants exclusively fed human milk were contributed by only three centres (study A), whereas the formula-fed infants were contributed by all five centres (studies A and B). The frequency of necrotising enterocolitis in preterm formula-fed babies did not, however, differ significantly between studies A and B (7·9 *vs* 7·4%).

TABLE II—CHARACTERISTICS OF STUDY POPULATION

—	All cases	Confirmed cases
No (%) with gestation of:		
25–27 wk (n = 118)	20 *(16·9%)*	12 *(10·2%)*
28–30 wk (n = 314)	18 *(5·7%)*	11 *(3·5%)*
< 30 wk (n = 494)	13 *(2·6%)*	8 *(1·6%)*
No (%) with birthweight of:		
< 1000 g (n = 144)	18 *(12·5%)*	11 *(7·6%)*
1000–1500 g (n = 403)	23 *(5·7%)*	15 *(3·7%)*
> 1500 g (n = 379)	10 *(2·6%)*	5 *(1·3%)*
No (%) of cases with concomitant respiratory disease†*	36/51 *(71%)*	21/31 *(68%)*
Median (IQR) enteral feed volume before NEC	410 (140–1160)	390 (160–990)
Median (IQR) day of onset	12 (7–18)	11 (7–18)

NEC = necrotising enterocolitis, IQR = interquartile range.
*338 (39%) of the 875 infants without NEC had concomitant respiratory disease
†Ventilated for > 24 h in the first 72 h

TABLE III—NECROTISING ENTEROCOLITIS BY FEED GROUP

—	n	No (%) of cases	
		All cases	Confirmed cases
Formula only	236	24 (10·2%)	17 (7·2%)
Formula plus mother's milk	437	16 (3·7%)	11 (2·5%)
Human milk only	253	11 (4·3%)	3 (1·2%)

TABLE IV—LOGISTIC REGRESSION MODELS FOR FACTORS SIGNIFICANTLY RELATED TO FREQUENCY OF NECROTISING ENTEROCOLITIS

	All cases		Confirmed cases	
	t	Odds ratio (95% CI)	*t*	Odds ratio (95% CI)
Formula only *vs* breast milk + formula	3·37 (p < 0·001)	3·3 (1·6–6·8)	3·05 (p < 0·01)	3·5 (1·5–8·1)
Formula only *vs* breast milk only	3·06 (p < 0·01)	3·5 (1·5–8·1)	3·74 (p < 0·001)	10·6 (3·0–37·3)
Gestation*	3·06 (p < 0·01)	1·2 (1·1–1·4)	2·43 (p < 0·05)	1·2 (1·0–1·5)
Days of umbilical artery catheterisation†	2·97 (p < 0·01)	1 2 (1·1–1·3)	3·04 (p < 0·01)	1·2 (1·1–1·4)
Day of first feed‡	2·60 (p < 0 01)	1 2 (1·0–1·4)	2·23 (p < 0·05)	1·2 (1 0–1·4)
Haemoglobin 200 g/l	2·39 (p < 0·05)	2·4 (1·2–5·1)		
Respiratory distress§	2·31 (p < 0·05)	2·6 (1 1–6·2)		

*Odds ratio is for each week shorter.
†Odds ratio is for each day in first 10
‡Odds ratio is for each day earlier.
§Requiring > 24 h ventilation

Logistic regression was used to adjust for any differences between groups in factors that have been associated previously with necrotising enterocolitis. The large differences between diet groups were seen even after adjustment for length of gestation, birthweight, sex, birth asphyxia, previous blood transfusions, use of theophylline and frusemide, polycythaemia, respiratory disease, duration of umbilical artery catheterisation, age at first enteral feed, rate of incrementation of early feed volumes, and maternal steroid treatment. One centre in study B had a slightly higher incidence of necrotising enterocolitis than the others. However, adjustment for any centre effects did not reduce the significance of the dietary findings.

In logistic regression models for all cases of necrotising enterocolitis and for confirmed cases (table IV), the independent variables were those of the factors above that were significantly related to the occurrence of necrotising enterocolitis. Length of gestation, duration of umbilical artery catheterisation, and age at first enteral feed were signficant factors in both models, but in both the type of diet was the factor most strongly related to necrotising enterocolitis. For all cases of necrotising enterocolitis, a high haemoglobin concentration and respiratory distress were also significant factors.

TABLE V—RELATION BETWEEN FREQUENCY OF NECROTISING ENTEROCOLITIS AND GESTATION IN BABIES RECEIVING HUMAN MILK AND IN THOSE FED SOLELY ON FORMULA

—	All cases		Confirmed cases	
	Formula only	Human milk*	Formula only	Human milk*
Gestation				
25–27 wk	7/35 (20%)	13/83 (16%)	5/35 (14%)	7/83 (8%)
28–30 wk	7/83 (8%)	11/231 (5%)	5/83 (6%)	6/231 (3%)
31–33 wk	6/75 (8%)	3/263 (1%)	3/75 (4%)	1/263 (0·4%)
34–36 wk	4/43 (9%)	0/113	4/43 (9%)	0/113

*Breast milk alone or in combination with formula

The effect of length of gestation on the occurrence of necrotising enterocolitis differed significantly ($p < 0·02$) between infants fed formula only and those fed breast milk (either alone or in combination with formula). Thus, infants fed on formula only had little overall decline in the frequency of necrotising enterocolitis over the range of gestations studied (25–36 weeks) and no decline beyond 27 weeks. In contrast there was a sharp fall in the frequency of necrotising enterocolitis with length of gestation in infants receiving breast milk (table V); for example, by logistic regression the odds ratio for necrotising enterocolitis at 26 weeks compared with 32 weeks was 11·3 ($p < 0·001$). In the group of babies born at more than 30 weeks' gestation, there were only 3 (0·8%) cases among the 376 fed on human milk (1 confirmed) compared with 10 (8·5%) among the 118 fed on formula only (7 confirmed); the odds ratio was 11·5 (3·1–43; $p < 0·0001$) for all cases and 23·6 (2·9–194; $p < 0·0001$) for confirmed cases.

There was also interaction between diet and the day of first feeding ($p = 0·05$). In formula-fed babies delay in onset of the first feed was associated with a significantly lower incidence of necrotising enterocolitis, whereas in infants fed breast milk (alone or with formula) there was no such relation.

Discussion

During the past 15 years breast milk has been promoted for the feeding of preterm infants on the grounds that it may protect against necrotising enterocolitis. The few data to support this assertion are not, however, widely accepted.[4,14,23] Indeed, a failure to establish clear benefits for breast milk in neonatal intensive care may be one of the reasons for a loss of enthusiasm for its use. In this large, prospective, multicentre study, the choice of early diet was the major factor associated with necrotising enterocolitis. Confirmed necrotising enterocolitis was 6 times as common in babies fed formula only than in those fed breast milk only; it was 10 times as common after adjustment for a wide range of factors associated previously with the disease. Furthermore, the risk of necrotising enterocolitis was 3·5 times higher in exclusively formula-fed infants than in those fed breast milk and formula combined, which suggests that breast milk can have an important protective role even when used as a supplement to formula feeding.

26% of our infants with confirmed necrotising enterocolitis died. Prognosis may be improving,[27] though an optimistic estimate for mortality in necrotising enterocolitis is 15–25%. If the frequency of cases in infants fed human milk either alone or in conjunction with formula is taken as a baseline, the excess frequency in babies who received no breast milk was 5–6 per 100 under 1850 g birthweight. Over the past 8 years the proportion of mothers in Cambridge providing any breast milk for their low birthweight infants has fallen from 75% to 55% (unpublished). Our enquiries suggest that in major parts of the UK the proportion providing any breast milk is likely to be lower. Furthermore, most British human milk banks have been closed. Probably about 50% of babies in neonatal intensive care receive no breast milk at all. If our data can be taken as representative and reflect causality, necrotising enterocolitis could occur in about 500 infants each year in the UK solely on account of exclusive formula feeding—more than 150 of them would require major abdominal surgery and about 100 would die.

The type of human milk given did not seem to affect the incidence of necrotising enterocolitis, despite theoretical predictions, from animal models, that only raw milk is

protective. We suggest, in the light of the finding that oral immunoglobulin in formula-fed babies was prophylactic,[10] that breast milk may protect against necrotising enterocolitis by providing IgA in the gut lumen. Most IgA remains intact after milk pasteurisation.[28] Thus when mother's milk is unavailable, the use of pasteurised breast milk could have a valuable place in the initial establishment of enteral feeding in preterm infants.

An important factor in the widespread closure of milk banks has been concern over the possibility of transmission by way of breast milk of human immunodeficiency virus (HIV), though some investigators have suggested that routine pasteurisation of breast milk would destroy HIV,[31] and HIV transmission has never been reported in a preterm infant fed pasteurised donor milk. This theoretical risk should be set against our finding of greater morbidity in premature babies who receive no human milk.

It is likely that a relation between diet and necrotising enterocolitis could have been missed in many previous studies that have had inadequate sample size and power, or inadequate control and monitoring of dietary intake. Our multicentre study was prospective, dietary assignment was strictly applied, and dietary management was carefully recorded and regulated; necrotising enterocolitis was a predetermined outcome response and extensive data were collected concomitantly that allowed adjustment for potential confounding factors. The diagnostic criteria we used for necrotising enterocolitis were those proposed after a large British multicentre study[26] rather than the similar criteria suggested by Bell[25] and most used in North America. Our cases all strictly met the criteria for grade 1 or 2 disease, and all the affected infants were treated with intravenous antibiotics and complete cessation of enteral feeding. Those confirmed by the most stringent criteria were presented separately, since they would be generally accepted as unequivocal cases.

As expected, length of gestation was a significant factor for necrotising enterocolitis. Nevertheless, over the whole range of gestation studied (25–36 weeks) the overall fall in confirmed necrotising enterocolitis risk was slightly smaller than the difference between groups fed exclusively on formula and on human milk. Although hypoxia and ischaemia have not been shown by some investigators to be risk factors for necrotising enterocolitis,[1,2,7] we found, as others have,[4-6] that respiratory distress, duration of use of an umbilical artery catheter (which might impede mesenteric flow, since most units used "high" catheter positioning), and polycythaemia (which could cause hyperviscosity and impair gut blood flow) were independently related to a higher incidence of the disease. These factors were not as strongly linked as diet.

In babies fed breast milk (alone or with formula) there was a sharp decline in incidence of necrotising enterocolitis with length of gestation; beyond 30 weeks' there was only 1 confirmed case among 376 babies. In contrast, there was no decline in necrotising enterocolitis incidence among formula-fed infants from 28 to 36 weeks' gestation; indeed beyond 30 weeks' gestation the overall incidence of confirmed disease was 20 times that in infants who received some breast milk. We suggest that early introduction of breast milk into the diets of preterm infants could make necrotising enterocolitis beyond 30 weeks' gestation a rarity.

In infants fed breast milk timing of the first feed was not related to frequency of necrotising enterocolitis, but in formula-fed infants, delay in starting feeds was associated with a significant reduction—if enteral feeds were started on, for example day 9 rather than day 2, the risk of necrotising enterocolitis was reduced threefold. These data suggest that units offering only formula might reduce the frequency of necrotising enterocolitis by a more cautious approach to early feeding than would be needed if human milk was available.

In view of this strong link between diet and necrotising enterocolitis, feeding policies in neonatal units may need reappraisal. Active encouragement of mothers to provide at least some breast milk for their preterm infants, especially during the early weeks, seems justified. We recognise that such infants have increased nutritional requirements,[29,30] but these can be met by concomitant use of preterm formulas and by human milk fortification. Furthermore, we consider it valuable for a major neonatal referral unit to support a human milk bank, despite the difficulties of donor screening for HIV.

We thank Dr M. Bamford, Dr P. Crowle, Dr J. Dossetor, Dr R. Pearse, Dr A. Boon, and the staff of neonatal units in Cambridge, Ipswich, King's Lynn, Norwich, and Sheffield for their help and collaboration; Farley Health Products Limited for collaboration, supply of trial diets, and continuing financial assistance; and Dr O. Brooke for advice in preparing the paper.

REFERENCES

1. Stoll BJ, Kano WP, Glass RI, Nahmias AJ, Brannon AW. Epidemiology of necrotizing enterocolitis: a case-control study. *J Pediatr* 1980; **96:** 447–51.
2. Kliegman RM, Hack M, Jones P, Fanaroff AA. Epidemiological study of necrotizing enterocolitis among low-birthweight infants. *J Pediatr* 1982; **100:** 440–44.
3. Kliegman RM, Fanaroff AA. Neonatal necrotizing enterocolitis: a nine-year experience. I. Epidemiology and uncommon observations. *Am J Dis Child* 1981; **135:** 603–07.
4. Bunton GL, Durbin GM, McIntosh N, et al. Necrotizing enterocolitis: controlled study of 3 years' experience in a neonatal intensive care unit. *Arch Dis Child* 1977; **52:** 772–77.
5. Palmer SR, Thomas SJ, Cooke RWI, et al. Birthweight-specific risk factors for necrotising enterocolitis. *Commun Health* 1987; **41:** 210–14.
6. Smith MF, Borriello SP, Clayden GS, Casewell MW. Clinical and bacterial findings in necrotising enterocolitis: a controlled study. *J Infect* 1980; **2:** 23–31.
7. Yu VYH, Joseph R, Bajuk B, Orgill A, Astbury J. Perinatal risk factors for necrotising enterocolitis. *Arch Dis Child* 1984; **59:** 430–34.
8. Kleigman RM. Neonatal necrotizing enterocolitis: implications for an infectious disease. *Pediatr Clin North Am* 1979; **26:** 327–44.
9. Book LS, Overall JUC, Herbst JJ, Britt MR, Epstein B, Jung AL. Clustering of necrotizing enterocolitis: interruption by infection-control measures. *N Engl J Med* 1977; **297:** 984–86.
10. Eibl MM, Wolf HM, Furnkranz H, Rosenkranz A. Prevention of nectrotizing enterocolitis in low-birth-weight infants by IgA-IgG feeding. *N Engl J Med* 1988; **319:** 1–7.
11. Anderson C, Collin M, OKeefe J. A widespread epidemic of mild necrotizing enterocolitis of unknown cause. *Am J Dis Child* 1984; **138:** 979.
12. Santulli TV, Schullinger JN, Heird WC, et al. Acute necrotizing enterocolitis in infancy: a review of 64 cases. *Pediatrics* 1975; **55:** 376–87.
13. Goldman HI. Feeding and necrotizing enterocolitis. *Am J Dis Child* 1980; **134:** 553–55.
14. Eyal F, Sagi E, Arad I, Avital A. Necrotizing enterocolitis in the very low birthweight infant: expressed breast milk feeding compared with parenteral feeding. *Arch Dis Child* 1982; **57:** 274–76.
15. Book LS, Herbert JJ, Atherton SO, Jung AL. Nectrotizing enterocolitis in low-birth-weight infants fed an elemental formula. *J Pediatr* 1975; **87:** 602–05.
16. Willis DM, Chabot J, Radde IC, Chance GW. Unsuspected hyperosmolality of oral solutions contributing to necrotizing enterocolitis in very-low-birthweight infants. *Pediatrics* 1977; **60:** 535–38.
17. LaGamma EF, Ostertag SG, Birenbaum H. Failure of delayed oral feedings to prevent necrotizing enterocolitis. Results of studying very-low birth-weight neonates. *Am J Dis Child* 1985; **139:** 385–89.
18. De Curtis M, Paone C, Vetrano G, Romano G, Paludetto R, Ciccimarra F. A case control study of necrotizing enterocolitis occurring over 8 years in a neonatal intensive care unit. *Eur J Pediatr* 1987; **146:** 398–400.

19. Kliegman RM, Pittard WB, Fanaroff AA. Necrotizing enterocolitis in neonates fed human milk. *J Pediatr* 1979; **95:** 450–53.
20. Kosloske AM. Pathogenesis and prevention of necrotizing enterocolitis: a hypothesis based on personal observation. *Pediatrics* 1984; **74:** 1086–92.
21. Barlow B, Santulli TV, Heird WC, Pitt J, Blanc WC, Schullinger JN. An experimental study of acute neonatal enterocolitis—the importance of breast milk. *J Pediatr Surg* 1974; **9:** 587–95.
22. Pitt J, Barlow B, Heird WC. Protection against experimental necrotizing enterocolitis by maternal milk. I. Role of milk leukocytes. *Pediatr Res* 1977; **11:** 906–09.
23. Moriartey RR, Finer NN, Cox SF, et al. Necrotizing enterocolitis and human milk. *J Pediatr* 1979; **94:** 295–96.
24. Lucas A, Gore SM, Cole TJ, et al. Multicentre trial on feeding low birthweight infants: effects of diet on early growth. *Arch Dis Child* 1984; **59:** 722–30.
25. Bell MJ, Ternberg JL, Feigin RD, et al. Neonatal necrotizing enterocolitis: therapeutic decisions based upon clinical staging. *Ann Surg* 1978; **187:** 1–7.
26. British Association for Perinatal Paediatrics and the Public Health Laboratory Service Communicable Disease Surveillance Centre. Surveillance of necrotising enterocolitis, 1981–82. *Br Med J* 1983; **287:** 824–26.
27. Black TL, Carr MG, Korones SB. Necrotizing enterocolitis: improving survival within a single facility. *South Med J* 1989; **82:** 1103–07.
28. Evans TJ, Ryley JC, Neale LM. Effect of storage and heat on antimicrobial proteins in human milk. *Arch Dis Child* 1978; **53:** 239–41.
29. Lucas A, Brooke OG, Baker BA, Bishop N, Morley R. High alkaline phosphatase activity and growth in preterm neonates. *Arch Dis Child* 1989; **64:** 902–09.
30. Lucas A, Morley R, Cole TJ. Early diet in preterm babies and developmental status at 18 months. *Lancet* 1990; **335:** 1477–81.
31. Eglin RP, Wilkinson AR. HIV infection and pasteurisation of breast milk. *Lancet* 1987; i: 1093.

Direct diagnosis of carriers of Duchenne and Becker muscular dystrophy by amplification of lymphocyte RNA

ROLAND G. ROBERTS DAVID R. BENTLEY TERESA F. M. BARBY
ELIZABETH MANNERS MARTIN BOBROW

Rapid detection of deletion and duplication mutations that cause Duchenne and Becker muscular dystrophy was achieved in patients and carriers after amplification of small amounts of mRNA from peripheral blood lymphocytes. The entire coding region of the dystrophin mRNA was amplified in 10 sections by reverse transcription and nested polymerase chain reaction, and the products were directly visualised on acrylamide minigels with ethidium staining. Major structural gene mutations were identified by the appearance of a band of different size to that of the wild type. The altered band was readily detected in all patients and heterozygous relatives. This non-radioactive test of venous blood samples can be used for unambiguous and rapid identification of virtually all carriers of deletions or insertions within the dystrophin gene.

Lancet 1990; **336:** 1523–26.

Introduction

Duchenne and Becker muscular dystrophies (DMD, BMD) are X-linked diseases which together affect about 1 in 3000 live male births. The dystrophin gene is very large and has an unusually high mutation rate; mutations in unrelated families are likely to be of independent origin and a third of all cases arise from new mutations.[1] About two-thirds of all affected infants have no family history of DMD or BMD; for such sporadic cases segregation analysis is usually uninformative and the carrier risk for related women is difficult to estimate.[2,3] Analysis of serum creatinine phosphokinase (CPK) concentrations[4] relies on the heterozygote's phenotypic expression and can give variable results; in conjunction with family data these yield Bayesian probabilities rather than definitive diagnosis.

In 65% of patients with DMD or BMD the disease-causing mutation consists of deletion or duplication of exons within the gene.[5] Such deletions are readily identified in patients by the absence of bands from Southern blots,[6,7] or by failure of amplification of individual reactions in multiplex polymerase chain reactions (PCRs).[8,9] However, diagnosis is complicated in carrier women by the presence of the normal chromosome, which masks the result from the defective chromosome. Carrier diagnosis (and duplication detection in patients) therefore requires dosage analysis by Southern blot[10] or PCR (Abbs S, et al, unpublished observations) in which the intensities of specific bands in different samples are compared. However, band intensity is dependent on various experimental factors, and carries a degree of uncertainty which many laboratories find unacceptable in clinical practice.

In 17% of patients with exon duplication or deletion the breakpoint is sufficiently close to a non-deleted exon that it lies within the restriction fragment detected by a cDNA probe on a Southern blot;[5] such a band of altered mobility can be detected in carrier women. The frequency of detection of such diagnostic junction fragments—which provide unequivocal identification of the mutation in carriers—can be greatly increased by the use of pulsed-field gel electrophoresis.[5,11] Such junction fragments may also be detected in mRNA: most deletion and duplication breakpoints lie within introns, which constitute over 99% of the dystrophin gene, so it is likely that transcription and transcript splicing are unaffected by the mutation. Thus a transcript from a defective gene would probably differ from the normal transcript only in that it bears a duplication or deletion of a number of exons. Amplification across the region of the mRNA which is duplicated or deleted should enable generation of a PCR product of anomalous size which is diagnostic of the presence of the defective gene.

Dystrophin mRNA is mainly expressed in muscle and brain, but Chelly et al[12] have shown that the dystrophin transcript is present in other tissues at about one copy per

ADDRESS: **Paediatric Research Unit, Division of Medical and Molecular Genetics, UMDS, Guy's Hospital, London SE1 9RT, UK** (R. G Roberts, BA, D. R Bentley, DPhil, T F. M. Barby, BSc, E Manners, BA, Prof M Bobrow, DSc) Correspondence to Mr R G. Roberts

EXHIBIT C

An Exclusively Human Milk-Based Diet Is Associated with a Lower Rate of Necrotizing Enterocolitis than a Diet of Human Milk and Bovine Milk-Based Products

Sandra Sullivan, MD, Richard J. Schanler, MD, Jae H. Kim, MD, PhD, Aloka L. Patel, MD, Rudolf Trawöger, MD, Ursula Kiechl-Kohlendorfer, MD, Gary M. Chan, MD, Cynthia L. Blanco, MD, Steven Abrams, MD, C. Michael Cotten, MD, MHS, Nirupama Laroia, MD, Richard A. Ehrenkranz, MD, Golde Dudell, MD, Elizabeth A. Cristofalo, MD, MPH, Paula Meier, PhD, Martin L. Lee, PhD, David J. Rechtman, MD, and Alan Lucas, MD

Objective To evaluate the health benefits of an exclusively human milk–based diet compared with a diet of both human milk and bovine milk–based products in extremely premature infants.

Study design Infants fed their own mothers' milk were randomized to 1 of 3 study groups. Groups HM100 and HM40 received pasteurized donor human milk–based human milk fortifier when the enteral intake was 100 and 40 mL/kg/d, respectively, and both groups received pasteurized donor human milk if no mother's milk was available. Group BOV received bovine milk–based human milk fortifier when the enteral intake was 100 mL/kg/d and preterm formula if no mother's milk was available. Outcomes included duration of parenteral nutrition, morbidity, and growth.

Results The 3 groups (total n = 207 infants) had similar baseline demographic variables, duration of parenteral nutrition, rates of late-onset sepsis, and growth. The groups receiving an exclusively human milk diet had significantly lower rates of necrotizing enterocolitis (NEC; $P = .02$) and NEC requiring surgical intervention ($P = .007$).

Conclusions For extremely premature infants, an exclusively human milk–based diet is associated with significantly lower rates of NEC and surgical NEC when compared with a mother's milk–based diet that also includes bovine milk–based products. *(J Pediatr 2010;156:562-7)*.

The health benefits of human milk for all infants, including those born extremely premature, have been increasingly recognized.[1] When compared with a diet of preterm formula, premature infants have improved feeding tolerance and a lower incidence of late-onset sepsis and necrotizing enterocolitis (NEC) when fed their mothers' milk.[2] It is a challenge for mothers of extremely premature infants, however, to provide sufficient milk to meet their infants' needs. In a recent study, only 30% of such mothers were able to supply 100% of their extremely premature infants' needs.[3] Pasteurized donor human milk would be an attractive proxy for mother's own milk, and donor milk banks have made milk available.[4] Indeed, a review of studies conducted in the 1980s, comparing donor human milk and formula, suggested that donor milk was associated with a significantly lower incidence of NEC.[5] Those studies, however, did not include a large proportion of extremely premature infants, and their nutritional protocols did not evaluate human milk fortifiers (HMF) or contemporary preterm formula.

A randomized trial compared fortified pasteurized donor human milk with preterm formula, both used as supplements when mother's own milk was not available.[3] That study did not find a protective effect of donor human milk on the combined incidence of late-onset sepsis and NEC but did note a significant

BOV	Bovine milk-based human milk fortifier
HMF	Human milk fortifier
HM40	Human milk-based HMF added once feeding volume reached 40 mL/kg/day, and pasteurized donor milk used if no mother's own milk available.
HM100	Human milk-based HMF added once feeding volume reached 100 mL/kg/day and pasteurized donor milk used if no mother's own milk available.
NEC	Necrotizing enterocolitis
PN	Parenteral nutrition
SD	Standard deviation

From the Department of Pediatrics, University of Florida (S.S.), Gainesville, FL; Department of Pediatrics, Schneider Children's Hospital at North Shore (R.S.), Manhasset, NY; Albert Einstein College of Medicine (R.S.), Bronx, NY; Department of Pediatrics, University of Rochester, Golisano Children's Hospital at Strong (N.L.), Rochester, NY; Department of Pediatrics, University of California, San Diego Medical Center (J.K.), San Diego, CA; Children's Hospital and Research Center (G.D.), Oakland, CA; Prolacta Bioscience (M.L., D.R.), Monrovia, CA; Pediatrics, Rush University Medical Center (A.P.), Chicago, IL; Department of Pediatrics, University of Utah Medical Center (G.C., P.M.), Salt Lake City, UT; Department of Pediatrics, University of Texas Health Science Center (C.B.), San Antonio, TX; Department of Pediatrics, Baylor College of Medicine (S.A.), Houston, TX; Department of Pediatrics, Duke University Medical Center (C.C.), Durham, NC; Pediatrics, Yale University School of Medicine (R.E.), New Haven, CT; Department of Pediatrics, Johns Hopkins School of Medicine (E.C.), Baltimore, MD; Department of Pediatrics, Innsbruck Medical University (R.T., U.K.), Innsbruck, Austria; and the MRC Child Nutrition Research Center, Institute of Child Health (A.L.), London, United Kingdom

S.S., R.J.S., J.H.K., A.L.P., R.T., U.K.-K., G.M.C., C.L.B., S.A., C.M.C., N.L., R.A.E., G.D., and E.A.C. received financial support from Prolacta Bioscience. The authors were responsible for the conduct of the study and collection of the data. M.L.L. and D.J.R. are employees of Prolacta Bioscience. A.L. is a paid Consultant of Prolacta Bioscience. P.M. received no support or payment. S.A., C.L.B., E.A.C., R.A.E., M.L.L., A.L., P.M., D.J.R., and R.J.S. were responsible for the design of the study. M.L.L. was responsible for the data analyses. R.J.S. wrote the draft of this manuscript. All of the authors were responsible for review and interpretation of the data and review of the manuscript.

Clinicaltrials.gov reg. # NCT00506584

 10.1016/j.jpeds.2009.10.040

protective effect of mother's own milk. The protocol in that study differed from previous studies in that the pasteurized donor human milk was fortified with bovine milk–based products, and some of the infants in the donor milk group were given preterm formula because of slower rates of growth. Thus no contemporary trial has investigated the effects of an exclusively human milk diet in extremely premature infants.

The technology now exists to collect, pasteurize, and process large quantities of screened donor human milk, labeled with its basic nutrient contents, and prepared as either a HMF or a donor milk alternative to mother's own milk.[6] This technology has prompted a randomized controlled trial in extremely premature infants to evaluate an exclusive human milk–based diet (that includes a human milk–based HMF and donor human milk if no mother's milk is available) compared with the usual feeding protocol comprising a mother's milk diet (that includes a bovine milk–based HMF and preterm formula if no mother's milk is available). We hypothesized that the health benefits (reduced duration of parenteral nutrition [PN], late-onset sepsis, and NEC) of an exclusively human milk–based diet would exceed those of the usual diet containing bovine milk–based products without detrimental effects on growth.

Methods

Infants were recruited from 12 neonatal intensive care units, 11 in the United States and 1 in Austria. Eligibility criteria were as follow: birth weight 500 to 1250 g, intention to receive mother's milk, and ability to adhere to a feeding protocol on the basis of the use of mother's own milk, initiation of enteral feeding before 21 days after birth, and initiation of PN within 48 hours of birth. Infants were excluded if there were major congenital malformations or a high likelihood of transfer to a non-study institution during the study period.

Randomization was performed in blocks of 4 on strata defined by birth weight (500 to 750 g, 751 to 1000 g, and 1001 to 1250 g), and whether the infant was appropriate- or small-for-gestational-age (defined as 2 standard deviations below the mean weight for gestational age on the basis of intrauterine growth charts[7]). Separate block randomization schemes were prepared for each of the strata and performed centrally. The investigators were not aware of the block size. The need to ensure proper handling of mother's own milk precluded true blinding of the infants' caregivers.

Sample size calculation was based on the primary outcome of duration of PN, a surrogate of feeding tolerance and neonatal morbidity. The mean duration of PN in extremely premature infants fed their mother's fortified milk was 18 ± 11 days (Meier and Blanco, personal communication). To demonstrate a 40% reduction in PN days in either study group, a sample size of 62 infants per group was needed for a 2-sided alpha error of 2.5% and power of 90%. To account for 2 interim analyses by the independent Data Safety Monitoring Board, and an estimated proportion of protocol nonadherence of 5%, the final sample was 69 infants per group. The study was approved by the institutional review boards of each center and written informed consent was obtained from the parents or legal guardians of all subjects before enrollment. Registered with Clinicaltrials.gov reg. # NCT00506584.

Infants were enrolled if their mothers intended to provide their own milk. When enteral nutrition was initiated, all study infants received their own mothers' milk but differed, as randomized, by the type of HMF they received and the type of milk they were given if no mother's own milk was available. Groups HM100 and HM40 received pasteurized donor human milk–based HMF (Prolact+ H^2MF; Prolacta Bioscience, Monrovia, California) when the enteral intake was 100 mL/kg/d and 40 mL/kg/d, respectively, and both groups received pasteurized and standardized 20 kcal/oz donor human milk (Neo20 Prolacta Bioscience) if no mother's milk was available. Group BOV received the usual feeding protocol of bovine milk–based HMF when the enteral intake was 100 mL/kg/d and preterm formula if no mother's own milk was available.

The duration of study participation was the earliest of the following milestones: 91 days of age, discharge from hospital, or attainment of 50% oral feedings (ie, 4 complete oral feedings per day). PN was initiated within 48 hours after birth. Trophic feedings were initiated 1 to 4 days after birth and were continued at 10 to 20 mL/kg/d as tolerated for up to 5 days. Subsequently, milk intake was increased by 10 to 20 mL/kg/d. Donor human milk–based HMF was added in the HM40 group when milk intake reached 40 mL/kg/d and in the HM100 group at 100 mL/kg/day. Bovine milk-based HMF (Enfamil HMF; Mead Johnson, Evansville, Indiana; or Similac HMF; Abbott Laboratories, Columbus, Ohio) was added in the BOV group when milk intake reached 100 mL/kg/d. After the HMF was added, milk intake was increased daily by 10 to 20 mL/kg to a maximum of 160 mL/kg/d. The nutritional content of the fortified milks used in the study is described in **Table I** (available at www.jpeds.com).

Daily body weight and weekly recumbent length and head circumference were recorded. Bronchopulmonary dysplasia was defined as the use of supplemental oxygen at 36 weeks postmenstrual age. Late-onset sepsis was defined as clinical signs and symptoms consistent with sepsis occurring more than 5 days after birth in association with the isolation of a causative organism from a blood culture.[3] In cases of coagulase-negative *Staphylococcus*, at least 2 separate positive cultures were required. NEC was defined as Bell Stage II disease or greater, and abdominal radiographs were read by radiologists unaware of study group assignment.[8] At the conclusion of the study, all cases of NEC were reviewed in a blinded fashion by a panel of 8 of the study investigators. Feeding intolerance was defined as gastric residuals greater than 50% of the prior feeding or more than 2 mL/kg, bile- or blood-stained gastric residuals, emesis, abdominal distention or tenderness, changes in stool pattern or consistency, presence of blood in the stool. Feeding intolerance was quantitated by

the number of days that feedings were withheld for ≥12 hours.

Statistical Analyses

The 3 study groups were compared by use of an intent-to-treat paradigm, any randomized infant remained in their group for the final analyses. Kaplan-Meier[9] estimates for the distribution of PN days were compared among study groups with the log-rank test. The Wilcoxon rank-sum test was used for 2-way comparisons. Three-way comparisons used either the 1-way analysis of variance for normally distributed data or the Kruskal-Wallis test for nonnormal data. Categorical data were compared by use of the χ^2 test with the *P* value determined by an exact procedure (StatXact 7; Cytel Software Corporation, Cambridge, Massachusetts).

Results

During the 14 months of the study, 334 infants were screened, and 207 were enrolled (Figure 1). The baseline characteristics of infants among the 3 study groups were similar (Table II). The ages of attainment of first enteral feeding (15, 11, and 16 days) and full (140 mL/kg/d) enteral feeding (21, 23, and 22 days) were similar among HM100, HM40, and BOV groups, respectively. There were no significant differences among study groups for the duration of PN, length of hospital stay, late-onset sepsis, or growth (Table III). The number of infants below the third percentile[7] at birth and at discharge was similar among groups.

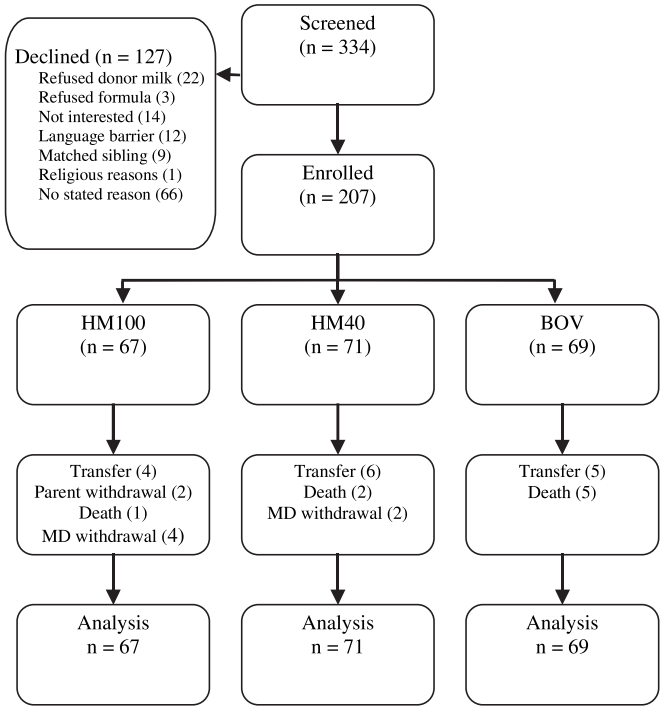


Figure 1. Distribution of study subjects.

Because there were no differences between HM100 and HM40, the exclusive HM group (HM100 + HM40) was compared with the BOV group. This analysis revealed similarities in baseline data and most outcomes, with the exception that there were fewer black infants in the BOV group compared with the combined HM100 + HM40 groups, 14% versus 27%, $P = .046$, and that the rate of weight gain was greater in the BOV group compared with the HM100 + HM40 groups, 16.0 ± 7.8 vs 14.3 ± 3.8 g/kg/d, $P = .051$.

Significant differences, however, were observed among study groups for the incidence of NEC (Figure 2). When compared with the BOV group, there were fewer cases of NEC in the HM100 and HM40 groups and the combined exclusive human milk–based diet groups (HM100 + HM40). A significant difference among groups was observed for the combined outcome of NEC or death in HM100 (6%), HM40 (8.5%), and BOV (20%), respectively, $P = .02$. The onset of NEC was similar among groups, 35 ± 18, 41 ± 18, 28 ± 12 postnatal days and 31 ± 1, 32 ± 3, and 31 ± 2 weeks postmenstrual age, in Groups HM100, HM40, and BOV, respectively. The number of cases of NEC requiring surgical intervention was significantly lower in the HM100 and HM40 groups compared with BOV group (Figure 2). All cases of surgical NEC occurred in infants who received bovine milk-based milk products (either HMF or preterm formula) at some time before the onset of NEC (Table IV; available at www.jpeds.com). Seven of these infants were randomized to the BOV group, but 2 of these infants were in the HM100/HM40 groups who had received bovine milk-based HMF or formula in violation of the protocol.

The 19 cases of NEC were distributed as 1 to 4 cases per site among 9 of the study sites. When rates of NEC were tabulated for only infants who completed the study without any protocol violations, the same distribution of cases was observed: 1.7%, 3.2%, and 15.3%, in HM100, HM40, and BOV groups, respectively; $P = .006$. A multivariate logistic regression that controlled for confounding variables known to affect the incidence of NEC (5-minute APGAR score, quantity of mother's own milk received, gestational age, receipt of prenatal and postnatal steroids, black race, bronchopulmonary dysplasia[10,11]) found an odds ratio for NEC with an exclusive human milk diet of 0.23 (95% confidence interval = 0.08, 0.66), $P = .007$, or a 77% reduction in the odds of developing NEC while receiving an exclusive human milk diet. None of the other variables reached statistical significance.

Infants in all 3 groups received a large volume and proportion of their enteral intake as their own mother's milk (Table III). The BOV group received significantly more own mother's milk because the fortifier was a powdered preparation whereas a liquid fortification regimen was used in the exclusive human milk groups.

Discussion

We conducted a randomized controlled multicenter trial to evaluate the potential health benefits of an exclusively human milk diet in extremely premature infants, 500 to

Table II. Characteristics of study infants

Parameter	HM100 (n = 67)	HM40 (n = 71)	BOV (n = 69)	*P* value
Birth weight, g	945 ± 202*	909 ± 193	922 ± 197	.56
Gestational age, wk	27.2 ± 2.2	27.1 ± 2.3	27.3 ± 2.0	.93
Male/Female, n (%)	32/35 (48/52)	25/46 (35/65)	36/33 (52/48)	.11
Small-for-gestational age, n (%)	6 (9)	6 (8)	8 (12)	.80
APGAR Score < 6, n (%)	9 (13)	4 (6)	8 (12)	.28
Black race n (%)	20 (30)	17 (24)	10 (14)	.10
Antenatal steroids, n (%)	56 (83)	51 (72)	53 (77)	.26
Mechanical ventilation at study entry, n (%)	49 (73)	56 (79)	53 (77)	.73

*Mean ± SD.

1250 g birth weight. This study was unique for its use of human milk–based human milk fortification. We were unable to demonstrate significant differences among the groups for the primary health outcome, PN days, a surrogate measure for feeding tolerance and early morbidity. Furthermore, we did not find significant differences in several other clinical outcomes. We speculate that the lack of differences is a direct result of the overall high intake of mother's own milk, which comprised more than 70% of enteral nutrition across all study groups. The high human milk intake reflects contemporary trends of improved lactation support and caregiver awareness and is consistent with the impact of human milk studies on this measure.[2,12,13]

Surprisingly, the rates of NEC and NEC requiring surgery were markedly lower in the groups fed human milk exclusively (HM100 and HM40) compared with the BOV group. We found a reduction in NEC of 50% and surgical NEC of almost 90% in infants fed an exclusive human milk diet compared with a diet containing bovine milk–based products. We estimate that the number of infants needed to treat with an exclusively human milk–based diet to prevent 1 case of NEC is 10. The number needed to treat to prevent 1 case of surgical NEC or death is 8. No other intervention has been shown to have such a marked effect on the incidence of NEC.[14] The mean incidence of NEC in the Vermont-Oxford Database (2007), approximately 7% to 10%, is in the range observed in this study. A 50% reduction in NEC would prevent between 1300 to 1850 cases annually, with each case leading to a high risk of death and long-term morbidity, and a hospitalization cost estimated at $138 000 to $238 000 per case.[4,15]

The lower incidence and severity of NEC in infants fed an exclusively human milk diet seen in our study are consistent with earlier reports. In 1990, Lucas and Cole[16] reported a reduction in the incidence of NEC among infants who received only human milk when compared with infants who received all bovine milk–based formula. Those infants who received a mixture of formula and human milk had an intermediate level of protection. Lucas[17] also reported a lower incidence of surgical NEC in infants fed unfortified compared with bovine milk-based fortified human milk. Lastly, 3 published meta-analyses concluded that donor human milk feeding was associated with less NEC.[5,18,19]

Our data contrast those reported in 2005,[3] which failed to find a protective effect of donor human milk on the combined incidence of sepsis and NEC, but reported that mother's own milk with bovine milk–based HMF was protective. That study, which also was analyzed on the intent-to-treat principle, included infants randomized to receive donor milk who were given formula because of poor growth, and all infants received a bovine milk–based fortifier. In 1984 Narayanan[20] reported a greater number of infections in premature infants fed pasteurized donor milk when they were also exposed to bovine milk-based formula. She concluded that pasteurized

Table III. Study outcomes

Outcome	HM100 (n = 67)	HM40 (n = 71)	BOV (n = 69)	*P* value
Parenteral nutrition, days	20* (14, 35)	20 (12, 33)	22 (14, 34)	.71
Length of stay, days	74 (61, 107)	79 (64, 110)	78 (67, 99)	.90
Mother's own milk, mL per study	4048 (841, 7479)	4544 (627, 8012)	5676 (1064, 8309)	.71
Mother's own milk, % enteral intake	73 (16, 82)	70 (18, 80)	82 (38, 100)	.002
Late-onset sepsis (LOS), n (%)	19 (28)	15 (21)	13 (19)	.39
LOS and/or NEC, n (%)	22 (33)	20 (28)	21 (30)	.84
Retinopathy of prematurity, n (%)	31 (46)	25 (35)	27 (39)	.41
Ventilator, days	25 (6, 54)	25 (12, 50)	34 (10, 58)	.54
Oxygen therapy, days	41 (24, 63)	48 (12, 78)	45 (19, 74)	.92
Central line, days	21 (15, 36)	22 (14, 30)	22 (16, 30)	.82
Bronchopulmonary dysplasia, n (%)	22 (33)	26 (37)	27 (39)	.74
Weight gain, (g/kg/day)	14.2 (11.9, 15.8)	14.2 (12.3, 16.3)	15.1 (12.8, 17.0)	.13
Length increment, (cm/wk)	0.86 (0.72, 1.08)	0.88 (0.70, 1.03)	0.94 (0.72, 1.16)	.35
Head circumference increment, cm/wk	0.76 (0.62, 0.85)	0.75 (0.61, 0.88)	0.75 (0.62, 0.86)	.99

*Median (25^{th}, 75^{th} percentile).

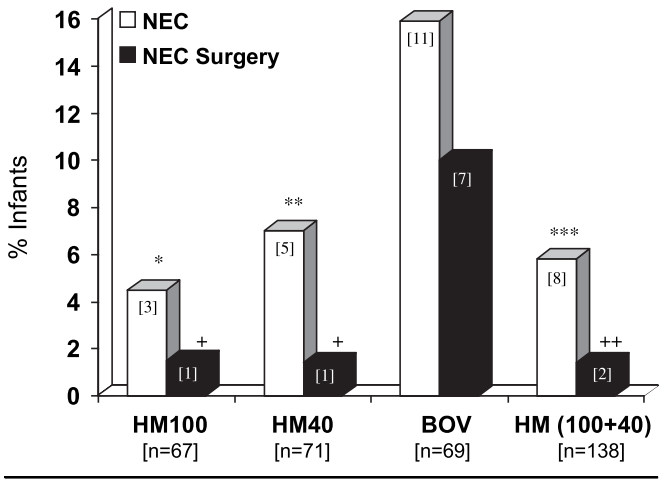


Figure 2. NEC and NEC surgery in study infants. There were significant differences in NEC among the 3 groups ($P = .05$), $^{*}P = .04$ vs BOV, $^{**}P = .09$ vs BOV, $^{***}P = .02$ vs BOV. There were significant differences in NEC requiring surgical intervention among the 3 groups ($P = .02$), $^{\dagger}P = .03$ vs BOV, $^{\dagger\dagger}P = .007$ vs BOV. [ ] refers to number of infants.

donor milk was effective only if it was fed as the total source of enteral nutrition.[21] These data suggest that exclusive human milk diets may exert protective, rather than threshold, effects with respect to NEC. The feeding of a species-specific diet may be important for this protection. However, we cannot exclude the possibility that the protective effect primarily was due to the avoidance of non human milk–based protein. Indeed, an animal model for NEC requires intraluminal bovine casein to produce the enterocolitis.[22]

This study also introduced an earlier fortification strategy with human milk–based human milk fortifier (HM40) to assess, secondarily, if such early fortification could be tolerated without introducing added morbidity. The 71 infants receiving the early fortification strategy appeared to tolerate the feeding well and did not differ significantly in feeding tolerance or other outcomes from the HM100 group. These are encouraging data that suggest the possibility of earlier introduction of human milk–based fortification compared with the usual practice of adding HMF at an enteral intake of 100 mL/kg/d.

The strengths of this study include a randomization and stratification scheme that achieved a balance of patient characteristics across the study groups and good adherence to the protocol as evidenced by a very small number of protocol violations. The control group correctly mimicked how extremely premature infants are fed, by use of combinations of mother's own milk and bovine-based products (HMF and formula). Limitations include the lack of complete blinding, which was not possible because of the obvious physical differences in human milk and formula and the limited power to look at subgroups, including those defined by sex and birth weight.

We conclude that for extremely premature infants, an exclusively human milk–based diet is associated with a significant reduction in the rates of NEC and surgical NEC compared with dietary exposure to bovine milk–based products. The similarities in other outcomes and the lower rate of NEC among study groups add support to the use of an exclusively human milk–based diet. The newer technology that enables an exclusively human milk diet with human milk–based fortification is now available to assist the ongoing efforts of neonatologists in their advocacy of human milk to reduce neonatal morbidity rates. ■

Submitted for publication Apr 8, 2009; last revision received Sep 16, 2009; accepted Oct 29, 2009.

Reprint requests: Richard J. Schanler, MD, Division of Neonatal-Perinatal Medicine, North Shore University Hospital, 300 Community Dr, Manhasset, New York 11030. E-mail: schanler@nshs.edu.

References

1. American Academy of Pediatrics. Section on Breastfeeding. Breastfeeding and the use of human milk. Pediatrics 2005;115:496-506.
2. Schanler RJ, Shulman RJ, Lau C. Feeding strategies for premature infants: Beneficial outcomes of feeding fortified human milk vs preterm formula. Pediatrics 1999;103:1150-7.
3. Schanler RJ, Lau C, Hurst NM, Smith EO. Randomized trial of donor human milk versus preterm formula as substitutes for mothers' own milk in the feeding of extremely premature infants. Pediatrics 2005; 116:400-6.
4. Arnold LDW. The cost-effectiveness of using banked donor milk in the neonatal intensive care unit: Prevention of necrotizing enterocolitis. J Hum Lact 2002;18:172-7.
5. Boyd CA, Quigley MA, Brocklehurst P. Donor breast milk versus infant formula for preterm infants: a systematic review and meta-analysis. Arch Dis Child Fetal Neonatal Ed 2007;92:F169-75.
6. Wojcik KY, Rechtman DJ, Lee ML, Montoya A, Medo ET. Macronutrient analysis of a nationwide sample of donor breast milk. J Am Diet Assoc 2009;109:137-40.
7. Alexander GR, Himes JH, Kaufman RB. A United States national reference for fetal growth. Obstet Gynecol 1996;87:163-8.
8. Walsh MC, Kliegman RM. Necrotizing enterocolitis: treatment based on staging criteria. Pediatr Clin North Am 1986;33:179-201.
9. Kaplan EL, Meier P. Nonparametric estimation from incomplete observations. J Am Stat Assoc 1958;53:457-81.
10. Guthrie SO, Gordon PV, Thomas V, Throp JA, Peabody J, Clark RH. Necrotizing enterocolitis among neonates in the United States. J Perinatology 2003;23:278-85.
11. Uauy RD, Fanaroff AA, Korones SB, Phillips EA, Phillips JB, Wright LL. Necrotizing enterocolitis in very low birth weight infants: Biodemographic and clinical correlates. J Pediatr 1991;119:630-8.
12. Furman L, Taylor G, Minich N, Hack M. The effect of maternal milk on neonatal morbidity of very low-birth-weight infants. Arch Pediatr Adolesc Med 2003;157:66-71.
13. Meinzen-Derr J, Poindexter B, Wrage L, Morrow AL, Stoll B, Donovan EF. Role of human milk in extremely low birth weight infants' risk of necrotizing enterocolitis or death. J Perinatol 2009;29:57-62.
14. Bell EF. Preventing necrotizing enterocolitis: what works and how safe? Pediatrics 2005;115:173-4.
15. Bisquera JA, Cooper TR, Berseth CL. Impact of necrotizing enterocolitis on length of stay and hospital charges in very low birth weight infants. Pediatrics 2002;109:423-8.
16. Lucas A, Cole TJ. Breast milk and neonatal necrotizing enterocolitis. Lancet 1990;336:1519-23.
17. Lucas A, Fewtrell MS, Morley R, Lucas PJ, Baker BA, Lister G, et al. Randomized outcome trial of human milk fortification and developmental outcome in preterm infants. Am J Clin Nutr 1996;64:142-51.
18. McGuire W, Anthony MY. Donor human milk versus formula for preventing necrotising enterocolitis in preterm infants: systematic review. Arch Dis Child Fetal Neonatal Ed 2003;88:F11-4.

19. Quigley MA, Henderson G, Anthony MY, McGuire W. Formula milk versus donor breast milk for feeding preterm or low birth weight infants (review). Cochrane Database of Systematic Reviews 2007;1-41.
20. Narayanan I, Prakash K, Murthy NS, Gujral VV. Randomised controlled trial of effect of raw and holder pasteurised human milk and of formula supplements on incidence of neonatal infection. Lancet 1984;ii:1111-3.
21. Narayanan I, Gupta J. Human milk and neonatal infections. Acta Paediatr Scand Suppl 1989;351:126-30.
22. Koivusalo A, Kauppinen H, Anttila A, Rautelin H, Jusufovic J, Lindahl H, et al. Intraluminal casein model of necrotizing enterocolitis for assessment of mucosal destruction, bacterial translocation, and the effects of allopurinol and N-acetycysteine. Pediatr Surg Int 2002;18:712-7.

Table I. Computed energy and macronutrient contents of milks (per dL)

Component	Mother's own milk*	Mother's own milk fortified with Prolacta fortifier†	Mother's own milk fortified with Similac HMF*	Mother's own milk fortified with Enfamil HMF‡
Energy (kcal)	67	83	79	81
Protein (g)	1.4	2.3	2.3	2.5
Carbohydrate (g)	6.6	7.3	8.2	7
Fat (g)	3.9	4.9	4.1	4.9
Calcium (mg)	25	110	138	115
Phosphorus (mg)	13	59	78	63
Osmolality§ (mOsm/kg H_2O)	290	< 360	est 385	325

*Abbott Nutrition, Columbus, Ohio. Product Description. 2009.
†Prolacta Bioscience, Monrovia, California. Product Description. 2009.
‡Mead Johnson Nutritionals, Evansville, Indiana. Product Description. 2009.
§NEOFAX 2009. Thomson Reuters, Montvale, New Jersey, pages 321-4.

Table IV. Characteristics of the NEC cases

Study group	Birth weight (g)	Gestational age (wk)	First day enteral feeding (day)	First day bovine milk-based HMF or formula (day)	First day human milk-based fortifier (day)	NEC onset (day)	Comment
HM100	720	25	5		32	35	
HM100	560	25	4	47*	20	53	NEC surgery
HM100	1105	28	3		9	18	
HM40	530	22	3		26	58	
HM40	740	25	9		17	38	
HM40	990	27	1	1*	7	22	NEC surgery†
HM40	785	28	1	77	3	60	
HM40	970	29	2	2*	5	25	
BOV	670	25	18	24		46	NEC surgery
BOV	690	25	1	1		17	NEC surgery
BOV	1170	26	1	11		25	NEC surgery
BOV	870	26	10	45	12‡	51	NEC surgery†
BOV	1136	27	1	13		18	NEC surgery
BOV	775	27	3	11		16	NEC surgery†
BOV	1120	28	5	16		38	
BOV	840	28	8	10		29	
BOV	1230	29	2	2		23	
BOV	1100	29	3	30		14	
BOV	817	29	2	12		26	NEC surgery

*Erroneously received formula or bovine milk-based HMF in violation of protocol.
†Died.
‡Erroneously received human milk-based HMF in violation of protocol.

EXHIBIT D

ANAPOL WEISS
BY: TRACY FINKEN, ESQUIRE
Identification Number: 82258
One Logan Square
130 N. 18th Street, Suite 1600
Philadelphia, PA 19103
(215) 735-0773
Email: tfinken@anapolweiss.com

ATTORNEY FOR PLAINTIFFS

Keller Lenkner LLC
BY: Ashley Keller (*pro hac vice forthcoming*)
150 N. Riverside Plaza, Suite 4100
Chicago, Illinois 60606
Telephone: (312) 741-5220
Fax: (312) 971-3502
Email: ack@kellerlenkner.com

ATTORNEY FOR PLAINTIFFS

Walsh Law PLLC
BY: Alex Walsh (*pro hac vice forthcoming*)
1050 Connecticut Ave, NW, Suite 500
Washington, D.C. 20036
Telephone: (202) 780-4127
Fax: (202) 780-3678
Email: awalsh@alexwalshlaw.com

ATTORNEY FOR PLAINTIFFS

ALICE STILLS, on her own behalf and as Parent and Natural Guardian of M.E., a Minor **656 N. Conestoga Street** **Philadelphia, PA 19131** **Plaintiffs**	:	**COURT OF COMMON PLEAS** **PHILADELPHIA COUNTY**
v.	:	**CIVIL ACTION**
MEAD JOHNSON & COMPANY, LLC **Illinois Corporation Service Co.** **801 Adlai Stevenson Drive** **Springfield, IL 62703**	:	
	:	**NO.**
MEAD JOHNSON NUTRITION COMPANY **Illinois Corporation Service Co.** **801 Adlai Stevenson Drive** **Springfield, IL 62703**	:	
ABBOTT LABORATORIES **CT Corporation System** **208 So. Lasalle Street, Suite 814** **Chicago, IL 60604**	:	

THE PENNSYLVANIA HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM d/b/a PENNSYLVANIA HOSPITAL **3400 Civic Center Blvd.** **Philadelphia, PA 19104**	:	
THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA d/b/a PENN MEDICINE **133 South 36th Street** **Philadelphia, PA 19104**	:	
Defendants	:	**JURY TRIAL DEMANDED**

COMPLAINT IN CIVIL ACTION

NOTICE TO DEFEND

NOTICE

You have been sued in court. If you wish to defend against the claims set forth in the following pages, you must take action within twenty (20) days after this complaint and notice are served, by entering a written appearance personally or by attorney and filing in writing with the court your defenses or objections to the claims set forth against you by the court without further notice for any money claimed in the complaint or for any other claim or relief requested by the plaintiff. You may lose money or property or other rights important to you.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER OR CANNOT AFFORD ONE, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW TO FIND OUT WHERE YOU CAN GET LEGAL HELP.

PHILADELPHIA BAR ASSOCIATION
LAWYER REFERRAL AND INFORMATION SERVICE
ONE READING CENTER
PHILADELPHIA, PA 19107
TELEPHONE: (215) 238-1701

AVISO

Le han demandado a usted en la corte. Si usted quiere defenderse de estas demandas expuestas las páginas siguientes, usted tiene viente (20) dias de plazo al partir de la fecha de la demanda y la notificación. Hace falta asentar una comparencia escrita o en persona o con un abogado y entregar a la corte en forma escrita sus defensas o sus objeciones a las demandas en contra de su persona. Sea avisado que si usted no se defiende, la corte tomará medidas y puede continuar la demanda en contra suya sin previo aviso o notificación. Además, la corte puede decidir a favor del demandante y requiere que usted cumpla con todas las provisiones de esta demanda. Usted puese perder dinero o sus propiedades u ostros derechos importantes para usted.

LLEVE ESTA DEMANDA A UN ABOGADO IMMEDIATAMENTE. SI NO TIENE ABOGADO O SI NO TIENE EL DINERO SUFICIENTE DE PAGAR TAL SERVICO, VAYA EN PERSONA O LLAME POR TELEPHONO A LA OFICINA CUYA DIRECCION SE ENCUENTRA ESCRITA ABAJO PARA AVERIGUAR DONDE SE PUEDE CONSEGUIR ASISTENCIA LEGAL.

ASOCIACION DE LICENCIADOS DE FILADELFIA
Servicio De Referencia E Información Legal
One Reading Center
Filadelfia, Pennsylvania 19107
Telephono: (215) 238-1701

ANAPOL WEISS
BY: TRACY FINKEN, ESQUIRE
IDENTIFICATION NUMBER: 82258
ONE LOGAN SQUARE
130 N. 18TH STREET, SUITE 1600
PHILADELPHIA, PA 19103
(215) 735-0773
EMAIL: TFINKEN@ANAPOLWEISS.COM — **ATTORNEY FOR PLAINTIFFS**

KELLER LENKNER LLC
BY: ASHLEY KELLER (*PRO HAC VICE FORTHCOMING*)
150 N. RIVERSIDE PLAZA, SUITE 4100
CHICAGO, ILLINOIS 60606
TELEPHONE: (312) 741-5220
FAX: (312) 971-3502
EMAIL: ACK@KELLERLENKNER.COM — **ATTORNEY FOR PLAINTIFFS**

WALSH LAW PLLC
BY: ALEX WALSH (*PRO HAC VICE FORTHCOMING*)
1050 CONNECTICUT AVE, NW, SUITE 500
WASHINGTON, D.C. 20036
TELEPHONE: (202) 780-4127
FAX: (202) 780-3678
EMAIL: AWALSH@ALEXWALSHLAW.COM — **ATTORNEY FOR PLAINTIFFS**

ALICE STILLS, ON HER OWN BEHALF AND AS PARENT AND NATURAL GUARDIAN OF M.E., A MINOR **656 N. CONESTOGA STREET** **PHILADELPHIA, PA 19131** **PLAINTIFFS**	:	**COURT OF COMMON PLEAS** **PHILADELPHIA COUNTY**
V.	:	**CIVIL ACTION**
MEAD JOHNSON & COMPANY, LLC **ILLINOIS CORPORATION SERVICE CO.** **801 ADLAI STEVENSON DRIVE** **SPRINGFIELD, IL 62703**	:	**NO.**
MEAD JOHNSON NUTRITION COMPANY **ILLINOIS CORPORATION SERVICE CO.** **801 ADLAI STEVENSON DRIVE** **SPRINGFIELD, IL 62703**	:	
ABBOTT LABORATORIES **CT CORPORATION SYSTEM** **208 SO. LASALLE STREET, SUITE 814** **CHICAGO, IL 60604**	:	
THE PENNSYLVANIA HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM D/B/A PENNSYLVANIA	:	

HOSPITAL **3400 CIVIC CENTER BLVD.** **PHILADELPHIA, PA 19104**	:	
THE TRUSTEES OF THE UNIVERSITY OF PENNSYLVANIA D/B/A PENN MEDICINE **133 SOUTH 36TH STREET** **PHILADELPHIA, PA 19104**	:	
DEFENDANTS	:	**JURY TRIAL DEMANDED**

COMPLAINT

Plaintiff brings this Complaint and Demand for Jury Trial (the "Complaint") against Mead Johnson & Company, LLC, Mead Johnson Nutrition Company, and Abbott Laboratories (collectively "the Defendant Manufacturers"), and The Trustees of the University of Pennsylvania d/b/a Penn Medicine and Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital (collectively "Penn Medicine" or "Pennsylvania Hospital"), together "Defendants." Plaintiff alleges the following upon personal knowledge as to Plaintiff's own acts and experiences and upon information and belief, including investigation conducted by Plaintiff's attorneys, as to all other matters.

I. INTRODUCTION

1. This action arises out of the injuries suffered by a premature infant (the "Injured Infant") who was given the Defendant Manufacturers' cow's milk-based infant feeding products at Pennsylvania Hospital. Pennsylvania Hospital, managed by Penn Medicine, acquired and supplied the Defendant Manufacturers' products to the Injured Infant and negligently failed to warn of their unreasonably dangerous properties in a reasonable manner. This caused the Injured Infant to develop necrotizing enterocolitis ("NEC"), a life-altering and potentially deadly disease that largely affects premature babies who are given cow's milk-based feeding products. As a result,

the Injured Infant was seriously injured, resulting in long term health effects and accompanying harm to their parent ("the Plaintiff Parent").

2. Plaintiff brings these causes of action against Defendants to recover for injuries that are the direct and proximate result of the Injured Infant's consumption of the Defendant Manufacturers' unreasonably dangerous cow's milk-based infant feeding products, which were acquired and supplied without adequate warning to the Injured Infant at Pennsylvania Hospital, owned and operated by Penn Medicine.

II. PARTIES

3. Plaintiff Alice Stills is a natural adult person and a resident of Pennsylvania. Ms. Stills is the parent and natural guardian of M.E., a minor. Ms. Stills' address is 656 N Conestoga Street, Philadelphia, Pennsylvania 19131.

4. Defendant Mead Johnson Nutrition Company is a corporation, incorporated under the laws of the State of Delaware. Its principal place of business is Illinois. Defendant Mead Johnson & Company, LLC, is a limited liability company, organized under the laws of the State of Delaware. Its citizenship is that of its sole member, Mead Johnson Nutrition Company. Defendants Mead Johnson Nutrition Company and Mead Johnson & Company, LLC, (together, "Mead") are manufacturers of cow's milk-based infant feeding products and market many of these products under the "Enfamil" brand name.

5. Defendant Abbott Laboratories ("Abbott") is a corporation, incorporated under the laws of the State of Illinois. Its principal place of business is in Illinois. Abbott is a manufacturer of cow's milk-based infant feeding products and markets many of its products under the "Similac" brand name.

6. Defendant The Pennsylvania Hospital of the University of Pennsylvania Health System d/b/a Pennsylvania Hospital is a non-profit corporation incorporated and registered to do business under the laws of the Commonwealth of Pennsylvania. Its principal place of business is Philadelphia, Pennsylvania. Pennsylvania Hospital is a registered name of The Pennsylvania Hospital of the University of Pennsylvania Health System. The sole member of The Pennsylvania Hospital of the University of Pennsylvania Health System is The Trustees of the University of Pennsylvania.

7. Defendant The Trustees of the University of Pennsylvania d/b/a Penn Medicine is a non-profit corporation registered to do business in the Commonwealth of Pennsylvania. Its principal place of business is Philadelphia, Pennsylvania. Penn Medicine is a registered name of The Trustees of the University of Pennsylvania.

III. JURISDICTION AND VENUE

8. This Court has jurisdiction in this matter pursuant to 42 Pa. C.S.A. § 931. Defendants conduct authorized business in the Commonwealth of Pennsylvania. They have sufficient minimum contacts with and purposefully avail themselves of the markets of this Commonwealth. This suit arises out of Defendants' forum-related activities, such that the Court of Common Pleas of Philadelphia County's exercise of jurisdiction would be consistent with traditional notions of fair play and substantial justice.

9. Venue is proper in the Court of Common Pleas of Philadelphia County pursuant to Rules 1006(b), 1006(c)(1), and 2179(a) of the Pennsylvania Rules of Civil Procedure because Defendants are corporations or similar entities that regularly conduct business in Philadelphia County, which is also the county where Plaintiff's causes of action arose, and the county where the occurrences took place out of which Plaintiff's causes of action arose.

10. This action is not subject to the Compulsory Arbitration Program of the Court of Common Pleas of Philadelphia County because the amount in controversy, excluding interest and costs, is in excess of $50,000.

IV. FACTUAL ALLEGATIONS

M.E.'s NEC Diagnosis

11. M.E. was born prematurely at Pennsylvania Hospital in Philadelphia, Pennsylvania on September 28, 2007.

12. Upon information and belief M.E. was fed Similac and/or Enfamil cow's milk-based products by staff at Pennsylvania Hospital from shortly after his birth.

13. Upon information and belief shortly after M.E. first ingested the Defendant Manufacturers' products, he developed NEC.

Cow's Milk-Based Feeding Products Are Known to Cause NEC

14. NEC is a devastating disease that is the most frequent and lethal gastrointestinal disorder affecting preterm infants. NEC develops when harmful bacteria breach the walls of the intestine, causing portions of the intestine to become inflamed and often to die. Once NEC develops, the condition can progress rapidly from mild feeding intolerance to systemic and fatal sepsis. Up to 30 percent of NEC-diagnosed infants die from the disease.

15. Preterm and low-birth-weight infants are especially susceptible to NEC because of their underdeveloped digestive systems. Extensive scientific research, including numerous randomized controlled trials, has confirmed that cow's milk-based feeding products cause NEC in preterm and low-birth-weight infants, which in turn may lead to other medical complications, surgeries, long-term health problems, and death.

16. For example, in one randomized, multicenter study of 926 preterm infants, NEC was six to ten times more common in exclusively cow's milk formula-fed babies than in exclusively breast milk-fed babies and three times more common in babies who received a combination of formula and breast milk. For babies born at more than 30 weeks gestation, NEC was 20 times more common in those only fed cow's milk formula than in those fed breast milk.

17. Another randomized controlled trial showed that preterm babies fed an exclusive breast milk-based diet were 90% less likely to develop surgical NEC (NEC that requires surgical treatment), compared to preterm babies fed a diet that included some cow's milk-based products.

18. Yet another study that analyzed the data from a 12-center randomized trial concluded that fortification of breast milk with a cow's milk-based fortifier resulted in a 4.2-fold increased risk of NEC and a 5.1-fold increased risk of surgical NEC or death, compared to fortification with a breast milk-based fortifier.

19. A Surgeon General report, The Surgeon General's Call to Action to Support Breastfeeding, warns that, "for vulnerable premature infants, formula feeding is associated with higher rates of necrotizing enterocolitis." The report also states that premature infants who are not breastfed are 138% more likely to develop NEC.

20. The American Academy of Pediatrics, "an organization of 67,000 pediatricians committed to the optimal physical, mental, and social health and well-being for all infants, children, adolescents, and young adults," has advised that all premature infants should be fed either their mother's milk or, if their mother's milk is unavailable, pasteurized human donor milk. This recommendation is based on the "potent benefits of human milk," including "lower rates of . . . NEC."

21. A multicenter, randomized, controlled trial found that premature and low-birth-weight infants fed an exclusive breast milk-based diet suffered NEC only 3% of the time while premature and low-birth-weight infants receiving cow's milk-based formula suffered NEC 21% of the time.

22. Another study conducted a randomized comparison of extremely preterm infants who were given either (a) a diet of breast milk fortified with a breast milk-based fortifier or (b) a diet containing variable amounts of cow's milk-based products. The babies given exclusively breast milk products suffered NEC 5% of the time. The babies given cow's milk products suffered NEC 17% of the time.

Safer, Nutritionally Superior Alternatives To Cow's Milk-Based Products Exist

23. A range of options are available that allow preterm and low-birth-weight infants to be fed exclusively human milk-based nutrition. For example, in addition to the mother's own milk, an established network delivers pasteurized donor breast milk to hospitals nationwide. Moreover, hospitals have access to shelf-stable formula and fortifiers derived from pasteurized breast milk.

24. A diet based exclusively on breast milk and breast milk fortifiers provides all the nutrition necessary to support premature and low-birth-weight infants without the elevated risk of NEC associated with cow's milk-based products. For example, in a study analyzing preterm infants who were fed an exclusive breast milk-based diet until they reached 34 weeks, all 104 infants exceeded standard growth targets and met length and head-circumference growth targets, demonstrating that infants can achieve and mostly exceed targeted growth standards when receiving an exclusive breast milk-based diet. This is particularly true given the ability of breast milk-based fortifiers to provide the additional nutritional supplements necessary for adequate growth while receiving the protective benefits of a breast milk diet.

25. The Defendant Manufacturers' products not only pose a threat to infants' health, but also displace the breast milk they could otherwise receive. This displacement only increases infants' vulnerability to NEC, as studies show that breast milk protects against the disease. For example, a study analyzing 1,587 infants across multiple institutions concluded that an exclusive breast milk-based diet is associated with significant benefits for extremely premature infants and that it produced no feeding-related adverse outcomes.

26. For the above reasons, experts acknowledge that breast milk is the best source of nutrition for preterm infants and those at risk for NEC. Breast milk-based nutrition nourishes infants while creating a significantly lower risk of NEC.

27. At the time the Injured Infant was fed the Defendant Manufacturers' products, the science clearly demonstrated to Defendants that these products cause NEC and greatly increase the likelihood that a baby will develop NEC, leading to severe injury and often death.

28. Despite the scientific consensus that the Defendant Manufacturers' cow's milk-based products present a dire threat to the health and development of preterm infants, the Defendant Manufacturers have made no changes to their products or the products' packaging, guidelines, instructions, or warnings. Instead, they have continued to sell their unreasonably dangerous products. In addition, they incentivize hospitals that know the risks to use their products by providing them to the hospital for free or at a significant discount, in order that vulnerable infants and their families will become accustomed to using their products before discharge.

The Defendant Manufacturers' False And Misleading Marketing Regarding Cow's Milk-Based Infant Products

29. Abbott and Mead have aggressively marketed their cow's milk-based products as medically endorsed and nutritionally equivalent alternatives to breast milk, including prior to the Injured Infant's birth.

30. Abbott's and Mead's marketing approach includes targeting the parents of preterm infants while they are still in the hospital with messages that the Defendant Manufacturers' cow's milk formulas and fortifiers are necessary for the growth and development of their vulnerable children. Often these tactics implicitly discourage mothers from breastfeeding, which reduces the mother's supply of breast milk. None of the Defendant Manufacturers' marketing materials, including their promotional websites, reference the science showing how significantly their products increase the risk of NEC.

31. Numerous studies have shown the detrimental impact of formula advertising on the rates of initiation and continuation of breastfeeding, including studies that show that as "hand feeding" (non-breastfeeding) advertisements increase, reported breastfeeding rates decrease in the following year.

32. Undoubtedly aware of the impact of their advertising, the Defendant Manufacturers, along with other formula manufacturers, are willing to spend massive sums to disseminate their message, with one study estimating that formula manufacturers collectively spent $4.48 billion on marketing and promotion in 2014 alone.

33. Recognizing the abuse and dangers of infant formula marketing, in 1981, the World Health Assembly—the decision-making body of the World Health Organization—developed the International Code of Marketing of Breast-milk Substitutes ("the Code"), which required companies to acknowledge the superiority of breast milk, the negative effect on breastfeeding of introducing partial bottle-feeding, and the difficulty of reversing the decision not to breastfeed. The Code also forbade advertising or other forms of promotion of formula to the general public, as well as providing sample products to mothers or members of their families.

34. While Abbott and Mead acknowledge the Code on their websites and claim to support the effort to encourage mothers to breastfeed for as long as possible, this is little more than lip service. Instead, the Defendant Manufacturers' aggressive marketing exploits new parents' darkest fears—that the nutrition they are supplying to their child will not provide the best chance of survival—while wholly failing to warn that their products come with a significantly increased risk of NEC.

35. For example, Abbott's website, on a paged titled "Infant Formula Marketing," states: "We agree with the World Health Organization that breastfeeding provides the best nutrition for babies, and we support its goal to increase breastfeeding. We also recognize that for infants who aren't breastfed—for medical reasons or otherwise—infant formula is the only appropriate, safe alternative to meet babies' nutritional needs." This statement ignores the existence of donor milk, as well as human milk-based formula.

36. Abbott markets and sells multiple products specifically targeting preterm and low-birth-weight infants, including Liquid Protein Fortifier, Similac NeoSure, Similac Human Milk Fortifiers, Similac Special Care 20, Similac Special Care 24, Similac Special Care 24 High Protein, and Similac Special Care 30. In advertising these products, Abbott emphasizes the products' purported ability to assist underdeveloped babies in reaching their growth targets. For example, on the since-edited webpage regarding Similac NeoSure, Abbott noted: "Your premature baby didn't get her full 9 months in the womb, so her body is working hard to catch up. During her first full year, feed her Similac NeoSure, a nutrient-enriched formula for babies who were born prematurely, and help support her development." Yet, no mention was made of the accompanying significantly increased risk of NEC. At some point, the website was edited to remove this statement. However, upon information and belief, the statement remained on the website until at least December 2020.

37. Mead markets and sells multiple products specifically targeting premature infants, including Enfamil NeuroPro EnfaCare Infant Formula, Enfamil Premature Infant Formula 24 Cal High Protein, Enfamil Premature Infant Formula 30 Cal with Iron, Enfamil Premature Infant Formula 24 Cal with Iron, Enfamil Premature Infant Formula 20 Cal with Iron, Enfamil 24 Cal Infant Formula, and Enfamil Human Milk Fortifier (acidified liquid and powder). In advertising these products, Mead emphasizes the purported similarities between its formula and breast milk, while failing to include any information about the nutritional deficits and dangers that accompany formula use. For example, the since-edited webpage for Enfamil Enfacare stated: "Premature babies fed Enfamil® formulas during the first year have achieved catch-up growth similar to that of full term, breastfed infants" and noted that Enfamil formulas include "expert-recommended levels of DHA and ARA (important fatty acids found naturally in breast milk) to support brain and eye development."

38. One Enfamil advertisement, introducing a new product line called Enfamil NeuroPro, is entirely focused on favorably comparing Enfamil's formula to breast milk, without any mention of the product's extreme risks. Indeed, the terms "human milk" and "breast milk" are used 13 times in the advertisement, including in such statements as "for decades human milk has inspired the advancements in Enfamil formulas and now through extensive global research, we are taking an even closer look at human milk" and "only Enfamil NeuroPro has a fat blend of MFGM and DHA previously found only in breast milk." The webpage for the product has made similar manipulative claims, stating "Enfamil is backed by decades of breast milk research and multiple clinical studies" and it claims that "to create our best formulas, we collaborated on some of the most extensive breast milk studies to date[.]"

39. Formula manufacturers have long used their relationships with hospitals and the discharge process to encourage parents to substitute formula for breast milk. They offer free or reduced-cost formula to hospitals for use with infants before discharge. And they offer free formula, coupons, and even entire gift baskets to parents before their infants' discharge from the NICU or hospital.

40. Through this early targeting, the Defendant Manufacturers create brand loyalty under the guise of a "medical blessing," in hopes that new parents continue to use formula after they leave the hospital, resulting in increased expense for parents, significantly increased risk for babies, and increased profit for the Defendant Manufacturers. The Defendant Manufacturers' giveaways and gift baskets send confusing signals to mothers who are simultaneously being encouraged to breastfeed by their healthcare professionals, and they have been shown to negatively impact breastfeeding rates.

41. Further, when the Defendant Manufacturers recognized a shift in the medical community towards an exclusive breast milk-based diet for premature infants, Abbott developed a product called "Similac Human Milk Fortifier," and Mead developed "Enfamil Human Milk Fortifier." These names are misleading in that they suggest that the products are derived from breast milk, when, in fact, they are cow's milk-based products. One study, for example, found that only 8.8 percent of parents surveyed in the NICU interpreted "human milk fortifier" as potentially meaning a cow's milk-based product. The packaging appears as:

42. The Defendant Manufacturers have designed powerful misleading marketing campaigns to deceive parents into believing that: (1) cow's milk-based products are safe, including for preterm infants; (2) cow's milk-based products are equal, or even superior, substitutes to breast milk; (3) cow's milk-based products are necessary for proper growth and development of preterm infants; and (4) physicians consider the Defendant Manufacturers' cow's milk-based products to be a first choice. This marketing scheme is employed despite all Defendants knowing of and failing to warn of the extreme risk of NEC and death that cow's milk-based products pose to preterm infants like the Injured Infant.

The Defendant Manufacturers' Inadequate Warnings

43. Although Mead promotes an aggressive marketing campaign designed to convince parents that its cow's milk-based products are safe and necessary for the growth of a premature infant, the product is in fact extremely dangerous for premature infants. Enfamil products significantly increase the chances of a premature infant developing potentially fatal NEC.

44. The Enfamil products Mead markets specifically for premature infants are commercially available at retail locations and online. No prescription is necessary.

45. Despite knowing of the risk of NEC, the packaging of Mead's products does not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with Mead's products, or of the magnitude of this increased risk. Mead likewise did not provide instructions or guidance for how to avoid NEC.

46. Mead cites no medical literature or research to guide the use of its products.

47. Despite knowing of the risk of NEC, Mead did not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with its products, or of the magnitude of this increased risk. Mead likewise did not provide instructions or guidance for how to avoid NEC.

48. Mead deceived the public, parents, physicians, other medical professionals, and medical staff into believing that Enfamil products were a safe and necessary alternative, supplement and/or substitute to breast milk.

49. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Mead failed to require or recommend that medical professionals inform parents of the significant risk of NEC or to require that parental consent be obtained prior to the products being fed to their babies.

50. Like Mead, Abbott promotes an aggressive marketing campaign designed to make parents believe that its products are safe and necessary for the growth of premature infants, despite the products in fact being extremely dangerous for premature infants. Abbott's products significantly increase the chances of a premature infant getting potentially fatal NEC.

51. The products Abbott markets specifically for premature infants are available at retail locations and online. No prescription is necessary.

52. Despite knowing of the risk of NEC, Abbott did not warn of the significantly increased risk of NEC (and resulting medical conditions, and/or death) associated with its products, or of the magnitude of this increased risk. Abbott likewise did not provide instructions or guidance for how to avoid NEC.

53. Abbott deceived the public, parents, physicians, other medical professionals, and medical staff into believing that its products were a safe and necessary alternative, supplement and/or substitute to breast milk.

54. Despite knowing that its products were being fed to premature infants, often without the parents' informed consent, Abbott failed to require or recommend that medical professionals inform parents of the significant risk of NEC or to require that parental consent be obtained prior to the products being fed to their babies.

Penn Medicine's Failure to Warn

55. On information and belief, Penn Medicine, which operates Pennsylvania Hospital, was aware of the significantly increased risk of NEC and death associated with providing Abbott's and Mead's cow's milk-based products to its premature infant patients. It knew or should have known that feeding these cow's milk-based products can cause NEC in premature infants who otherwise would not have developed this devastating condition. However, instead of warning of those

dangers, or supplying breast milk-based feeding products to preterm infants like the Injured Infant, Penn Medicine has continued to source, distribute, and supply the Defendant Manufacturers' products in its hospitals without any adequate warning.

56. To that end, Penn Medicine has participated in studies designed to increase the use of donor milk while, at the same time, reducing formula feeding in neonates. The University of Pennsylvania School of Nursing, an affiliate of Penn Medicine, has conducted extensive research into the risks associated with feeding formula to premature infants. It recently partnered with the National Institute of Nursing Research to publish clinical determinations based on its experience "changing hospital systems and influencing policy," and its findings were unequivocal:

> This is what we know about the science of human milk: it reduces the risk of necrotizing enterocolitis, reduces the risk of infection, [and] creates greater enteral feed tolerance and more rapid weaning from intravenous nutrition. . . .

Other Penn Medicine research has similarly concluded that "[h]uman milk decreases the incidence and severity of . . . necrotizing enterocolitis (NEC)."

57. Penn Medicine also purports to adhere to the tenets of the "Baby Friendly Hospital Initiative," which seeks to increase rates of breastfeeding initiation, exclusivity, and diet duration. The "Baby Friendly Hospital Initiative" specifically targets a reduction in the rates of NEC in preterm infants by encouraging implementation of exclusive breast milk diets among new mothers. Although Pennsylvania Hospital has maintained its "Baby Friendly" designation for years, it has not eliminated or restricted the use of formula or fortifier for preterm infants in its hospitals.

58. Finally, medical providers and staff at Penn Medicine have acknowledged the risks associated with providing the Defendant Manufacturers' cow's milk-based products to premature infant patients instead of breast milk-based nutrition. In an internal newsletter from 2012 touting donor milk programs, Penn Medicine acknowledged the benefits of a human milk-based diet, quoting a staff lactation consultant:

> Donor milk is not inexpensive. It costs about $4.25 per ounce, but the return on investment is huge. "Preemies given mother's milk get discharged three to four days sooner and also have a six to 10 times lower risk of getting a gastrointestinal complication called necrotizing enterocolitis," Carpenter said, adding that the infection can cost up to $250,000 to treat. The average cost to provide a preemie with donor milk: $125.

59. These statements demonstrate that Penn Medicine knew or should have known of the high increased risk of NEC for premature infants posed by the Defendant Manufacturers' products.

60. Although Penn Medicine knew or should have known of the serious danger of the Defendant Manufacturers' products, it has continued to purchase, supply, and distribute these products to preterm infants without providing full and adequate warnings of the attendant risks to parents, healthcare professionals, and other medical staff at its relevant facilities. As a result, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products at Pennsylvania Hospital, causing their injuries. This occurred even though hospitals across the country, including Pennsylvania Hospital, warn and obtain consent from parents before providing other safer forms of nutrition, such as donor breast milk.

61. Penn Medicine's failure to warn of the risks posed by the Defendant Manufacturers' products is entrenched (and compounded) by the financial benefits it accrues from its relationships with the Defendant Manufacturers. On information and belief, it has received the Defendant Manufacturers' cow's milk-based products for free or at a significant discount, and has granted their sales representatives access to its healthcare professionals and medical staff. These sales representatives have provided deceptive information that Penn Medicine reasonably knew or should have known would ultimately reach parents through those staff. This arrangement dovetails with the Defendant Manufacturers' own marketing strategy, which aims to "sell and service" healthcare professionals and medical staff as a means of converting them into "extra salespersons."

Safer Alternative Designs

62. The Defendant Manufacturers' cow's milk-based products made specifically for premature infants are unreasonably unsafe for those infants. The Defendant Manufacturers could have used pasteurized breast milk instead of cow's milk in their products, which would have produced a safer product.

63. Prolacta Bioscience manufactures and sells breast milk-based feeding products, specifically designed for preterm infants, which contain no cow's milk. This alternative design provides all the necessary nutrition for growth and development that cow's milk-based products provide, without the same unreasonably dangerous and deadly effects.

64. On information and belief, Abbott and Mead were aware of the significantly increased risk of NEC and death associated with their cow's milk-based products, and instead of warning of the dangers, or removing them altogether, Abbott and Mead have continued to use cow's milk as the foundation of their products.

CAUSES OF ACTION
COUNT I: STRICT LIABILITY FOR DESIGN DEFECT
(Against Abbott and Mead)

65. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

66. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to manufacture, sell, and distribute their products in a manner that was not unreasonably dangerous.

67. Abbott and Mead also owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to manufacture, sell, and distribute their products in a manner that was merchantable and reasonably suited for their intended use.

68. Abbott and Mead knew that their products would be used to feed premature infants like the Injured Infant and knew (or reasonably should have known) that use of their cow's milk-based products significantly increased the risk of NEC, serious injury, and death, and that such use was therefore unreasonably dangerous to premature infants, not reasonably suited for the use intended, not merchantable, and had risks that exceeded a reasonable buyer's expectations. Nonetheless, they continued to sell and market their defective products as appropriate for premature infants.

69. The Injured Infant ingested Abbott and/or Mead's unreasonably dangerous cow's milk-based products. The risks of feeding those products to the Injured Infant outweighed the benefits. An ordinary consumer would not expect those products to carry a significant risk of serious injury and death from NEC.

70. Abbott and Mead knew (or reasonably should have known) that breast milk-based nutrition did not carry the same risks of NEC, serious injury, and death that their products do.

71. Abbott's and Mead's products contained cow's milk at the time they left the manufacturing facility.

72. Abbott and Mead did not develop a human-milk based product that was safer for premature infants and did not reformulate their products to reduce the risk of NEC, serious injury, and death, even though doing so was economically and technologically feasible and even though pasteurized breast milk was an available alternative.

73. Abbott's and/or Mead's products were fed to the Injured Infant, which caused and/or increased the risk of their NEC and injuries.

74. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

a. For compensatory damages in an amount to be proven at trial and in excess of $50,000 and this Court's arbitrational limit;

b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;

c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

d. For punitive damages in excess of $50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;

e. For interest as permitted by law;

f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and

g. For such other and further relief as the Court deems proper.

COUNT II: STRICT LIABILITY FOR FAILURE TO WARN
(Against Abbott and Mead)

75. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

76. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide adequate warnings or instructions about the dangers and risks associated with the use of

their products with preterm infants, specifically including but not limited to the risk of NEC, serious injury, and death.

77. Abbott's and Mead's duty to warn is part of their general duty to design, manufacture, and sell their infant products in a manner that is reasonably safe for their foreseeable uses. By designing their products with cow's milk-based ingredients, Abbott and Mead undertook a duty to warn of the unreasonable risk of harm posed by those ingredients, specifically including the significantly increased risk of NEC, severe injury, and death. The failure to warn makes the products at issue in this litigation unreasonably dangerous.

78. Specifically, Abbott and Mead breached their duty to warn of the foreseeable risks of the infant products at issue in this litigation because they knew or should have known that their cow's milk-based premature infant products would be fed to premature infants like the Injured Infant, and that their products might cause the Injured Infant to develop NEC, severe injury, or death, yet they failed to provide adequate warnings of those risks. Among other risks, the Defendant Manufacturers:

a. Failed to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death for the Injured Infant; and/or

b. Failed to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or

c. Inserted warnings and instructions on their products that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or

d. Failed to insert a large and prominent "black box"-type warning that their cow's milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infant; and/or

e. Failed to disclose well-researched and well-established studies that linked cow's milk-based products to NEC and death in premature infants; and/or

f. Failed to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risks; and/or

g. Failed to provide a warning in a method reasonably calculated or expected to reach the parents of newborns, like the Plaintiff Parent; and/or

h. Failed to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products.

79. Abbott's and Mead's products contained cow's milk at the time they left the manufacturing facility.

80. As a direct and proximate result of the inadequacy of the warnings and the pervasive marketing campaigns suggesting the safety and necessity of the Defendant Manufacturers' products, the Injured Infant were fed cow's milk-based products, which caused them to develop NEC.

81. The unwarned-of risks are not of a kind that an ordinary consumer would expect. Had physicians and medical staff known of the extreme risk associated with feeding premature infants cow's milk-based formula, they would not have fed the Injured Infant those products. Had the

Plaintiff Parent known of the significant risks of feeding the Injured Infant cow's milk-based formula, they would not have allowed such products to be fed to the Injured Infant.

82. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

a. For compensatory damages in an amount to be proven at trial and in excess of $50,000 and this Court's arbitrational limit;

b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;

c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

d. For punitive damages in excess of $50,000 and this Court's arbitrational limit resulting from the Defendants Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;

e. For interest as permitted by law;

f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and

g. For such other and further relief as the Court deems proper.

COUNT III: NEGLIGENCE
(Against Abbott and Mead)

83. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

84. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to exercise reasonable care to design, test, manufacture, inspect, and distribute a product free of unreasonable risk of harm to users, when such products are used in their intended manner and for their intended purpose.

85. At all times relevant to this action, the Injured Infant's healthcare professionals and medical staff used the products at issue in their intended manner and for their intended purpose.

86. Abbott and Mead, directly or indirectly, negligently, and/or defectively made, created, manufactured, designed, assembled, tested, marketed, sold, and/or distributed the cow's milk-based infant products at issue in this litigation and thereby breached their duty to the general public and the Plaintiff Parent.

87. Specifically, although Abbott and Mead knew or reasonably should have known at the time of production that their cow's milk-based infant products significantly increased the risk of NEC, serious injury, and death, they failed to act in a reasonably prudent manner and breached their duty by:

a. Failing to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death for the Injured Infant; and/or

b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or

c. Inserting warnings and instructions that are severely inadequate, vague, confusing, and provide a false sense of security in that they warn and instruct specifically on certain conditions, but do not warn of the significantly increased risk of NEC and death; and/or

d. Failing to insert a large and prominent "black box"-type warning that their cow's milk-based products are known to significantly increase the risk of NEC and death when compared to breast milk in premature infants; and/or

e. Failing to provide well-researched and well-established studies that linked cow's milk-based products to NEC and death in premature infants; and/or

f. Failing to insert a warning or instruction to healthcare professionals and other medical staff in the hospital that parents should be provided information necessary to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risks; and/or

g. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns, like the Plaintiff Parent; and/or

h. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products.

88. In addition, although Abbott and Mead knew or reasonably should have known at the time of production that their cow's milk-based products significantly increased the risk of NEC, serious injury, and death, they failed to act in a reasonably prudent manner and breached their duty by failing to perform the necessary process of data collection, detection, assessment, monitoring, prevention, and reporting or disclosure of adverse outcomes in infants who ingest their products.

89. As a direct and proximate result of the Defendant Manufacturers' failure to act in a reasonably prudent manner and their breach of duty, the Injured Infant was fed cow's milk-based products, which caused and/or increased the risk of their developing NEC.

90. Had Abbott and Mead satisfied their duties to the consuming public in general, the Injured Infant would not have been exposed to their unreasonably dangerous cow's milk-based products.

91. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

a. For compensatory damages in an amount to be proven at trial and in excess of $50,000 and this Court's arbitrational limit;

b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;

c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

d. For punitive damages in excess of $50,000 and this Court's arbitrational limit resulting from the Defendants Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;

e. For interest as permitted by law;

f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and

g. For such other and further relief as the Court deems proper.

COUNT IV: INTENTIONAL MISREPRESENTATION
(Against Abbott and Mead)

92. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

93. At all times relevant to this action, the Injured Infant consumed the Defendant Manufacturers' products in their intended manner and for their intended purpose.

94. Abbott and Mead, as the manufacturers and/or sellers of the infant products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide truthful, accurate, fulsome information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

95. Abbott and Mead breached their duty through misrepresentations made to consumers, physicians, and medical staff in their advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable and intended recipients of this information.

96. Specifically, upon information and belief, Abbott and Mead made the following false statements of material fact on an ongoing and repeated basis and prior to the time the Injured Infant was fed their products:

a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or

b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or

c. That their products have no serious side effects, when they knew or should have known the contrary to be true; and/or

d. That cow's milk-based products were safe for premature infants; and/or

e. That cow's milk-based products were necessary for optimum growth; and/or

f. That cow's milk-based products were similar or equivalent to breast milk; and/or

g. That their products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or

h. That their products were based on up-to-date science, which made them safe for premature infants; and/or

i. Omitting the material fact that their products significantly increased the risk of NEC in premature infants.

97. Abbott and Mead knew or reasonably should have known those misrepresentations to be false.

98. The Defendant Manufacturers' misrepresentations were intended to, and in fact did, induce physicians and medical staff, including the Injured Infant's physicians and medical staff, to provide their infant products to babies, including the Injured Infant.

99. The Plaintiff Parent was not aware that these misrepresentations were false and justifiably relied on them. The Defendant Manufacturers' misrepresentations induced the Plaintiff Parent to allow their children to be fed Abbott's and Mead's infant products, in reliance on all the messaging they received about formula feeding, including, directly or indirectly, the Defendant Manufacturers' messaging. Had Abbott and Mead not committed these intentional

misrepresentations, the Injured Infant would not have been exposed to the Defendant Manufacturers' unreasonably dangerous cow's milk-based products.

100. As a direct and proximate result, Abbott's and Mead's products were fed to the Injured Infant, which caused and/or increased risk of their developing NEC and subsequent injuries.

101. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

a. For compensatory damages in an amount to be proven at trial and in excess of $50,000 and this Court's arbitrational limit;

b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;

c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

d. For punitive damages in excess of $50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;

e. For interest as permitted by law;

f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and

g. For such other and further relief as the Court deems proper.

COUNT V: NEGLIGENT MISREPRESENTATIONS
(Against Abbott and Mead)

102. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

103. At all times relevant to this action, the Injured Infant consumed the products at issue in their intended manner and for their intended purpose.

104. Abbott and Mead, as the manufacturers and/or sellers of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to provide truthful, accurate, and complete information about the risks and benefits of using their products when used in the intended manner and for the intended purpose.

105. In the course of their business, Abbott and Mead breached their duty through misrepresentations made to consumers, physicians, and medical staff in their advertising and promotional materials, as described in previous paragraphs and incorporated herein, each of whom were foreseeable recipients of this information.

106. Specifically, upon information and belief, Abbott and Mead made the following false statements of material fact on an ongoing and repeated basis and prior to the time the Injured Infant was fed their products:

a. That their cow's milk-based products were safe and beneficial for premature infants when they knew or should have known that their products were unreasonably dangerous and cause NEC, serious injury, and death in premature infants; and/or

b. That their cow's milk-based products were necessary to the growth and nutrition of premature infants, when they knew or should have known that their products were not necessary to achieve adequate growth; and/or

c. That their products have no serious side effects, when they knew or should have known the contrary to be true; and/or

d. That cow's milk-based products were safe for premature infants; and/or

e. That cow's milk-based products were necessary for optimum growth; and/or

f. That cow's milk-based products were similar or equivalent to breast milk; and/or

g. That their products were safe and more like breast milk than other infant products and that they had removed the harmful ingredients of cow's milk when, in fact, the cow's milk in their products was still capable of causing NEC, serious injury, and death; and/or

h. That their products were based on up-to-date science, which made them safe for premature infants; and/or

i. Omitting the material fact that their products significantly increased the risk of NEC in premature infants.

107. Abbott and Mead were negligent or careless in not determining those representations to be false.

108. The Defendant Manufacturers' misrepresentations were intended to and did in fact induce physicians and medical staff, including the Injured Infant's physicians and medical staff, to provide their products to babies, including the Injured Infant.

109. The Defendant Manufacturers' misrepresentations induced, and were intended to induce, the Plaintiff Parent to allow their child to be fed Abbott's and Mead's infant products, in justifiable reliance on all the messaging they received about formula feeding, including, directly or indirectly, the Defendant Manufacturers' messaging. Had Abbott and Mead not committed these negligent

misrepresentations, the Injured Infant would not have been exposed to their unreasonably dangerous cow's milk-based products.

110. As a direct and proximate result, Abbott's and Mead's products were fed to the Injured Infant, which caused and/or increased of their developing NEC and subsequent injuries.

111. As a further direct result, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against the Defendant Manufacturers as follows:

a. For compensatory damages in an amount to be proven at trial and in excess of $50,000 and this Court's arbitrational limit;

b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of the Defendants Manufacturers' conduct;

c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

d. For punitive damages in excess of $50,000 and this Court's arbitrational limit resulting from the Defendant Manufacturers' oppressive, fraudulent, and/or malicious conduct, as permitted by law;

e. For interest as permitted by law;

f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and

g. For such other and further relief as the Court deems proper.

COUNT VI: FAILURE TO WARN
(Against Penn Medicine and Pennsylvania Hospital)

112. Plaintiff incorporates by reference each of the preceding paragraphs as if fully set forth herein.

113. Penn Medicine and Pennsylvania Hospital as purchaser, supplier, and/or distributor of the products at issue in this litigation, owed a duty to the consuming public in general, and the Plaintiff Parent in particular, to purchase, supply, and distribute products that were free of unreasonable risk of harm when used in their intended manner and for their intended purpose, and/or to formulate, adopt, and enforce adequate rules and policies for the same.

114. At all times relevant to this action, the Injured Infant used the cow's milk-based products purchased, supplied, and/or distributed by Penn Medicine and Pennsylvania Hospital in their intended manner and for their intended purpose.

115. Penn Medicine and Pennsylvania Hospital employed or contracted with the healthcare professionals and medical staff at Pennsylvania Hospital, managing these individuals during their treatment of the Injured Infant.

116. Penn Medicine and Pennsylvania Hospital negligently and recklessly supplied and distributed the Defendant Manufacturers' milk-based infant feeding products to these healthcare professionals and medical staff for use on premature infants, including the Injured Infant.

117. Moreover, at all relevant times, Penn Medicine and Pennsylvania IIospital knowingly authorized the Defendant Manufacturers' sales representatives to market, advertise, distribute, and/or sell their products at Pennsylvania Hospital. The Defendant Manufacturers' sales representatives were encouraged to interact with Pennsylvania Hospital's healthcare professionals and medical staff. These interactions provided the Defendant Manufacturers' sales representatives an opportunity to co-opt Pennsylvania Hospital's healthcare professionals and medical staff into

assisting with the marketing, distribution, and/or sale of the Defendant Manufacturers' unreasonably dangerous products to consumers, such as the Plaintiff Parent.

118. Penn Medicine and Pennsylvania also knowingly allowed the Defendant Manufacturers' sales representatives to routinely misrepresent the risks and benefits of Defendants' products to Pennsylvania Hospital's healthcare professionals and medical staff, including the misrepresentation that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

119. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known at the time that they acquired, distributed, and supplied the Defendant Manufacturers' cow's milk-based infant products that these products significantly increased the risk of NEC, serious injury, and death.

120. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, recklessly and breached its duty by:

a. Failing to warn that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or

b. Failing to warn that cow's milk-based products are unsafe and/or contraindicated for premature infants like the Injured Infant; and/or

c. Failing to warn or instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or

d. Failing to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or

e. Failing to provide a warning in a method reasonably calculated/expected to reach the parents of newborns; and/or

f. Failing to provide statistical evidence showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products; and/or

g. Failing to prevent the Defendant Manufacturers' sales representatives from misrepresenting to Pennsylvania Hospital's healthcare professionals and medical staff that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

121. Reasonable hospitals under the same or similar circumstances would have warned of the above risks, would have instructed their healthcare professionals and medical staff—as well as patients—on the safe use of the Defendant Manufacturers' products, and would have restricted the ability of the Defendant Manufacturers' sales representatives to market the Defendant Manufacturers' unreasonably dangerous products without adequate warning.

122. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that its medical professionals and the parents of premature infants, including the Plaintiff Parent, would not have realized the risks associated with feeding cow's milk-based formula to premature infants.

123. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to warn its medical providers and patients about the Defendant Manufacturers' unreasonably dangerous products, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

124. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to warn of the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

125. As a further direct and proximate result of Penn Medicine and Pennsylvania failure to warn of the Defendant Manufacturers' unreasonably dangerous products, the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against Penn Medicine and Pennsylvania Hospital as follows:

a. For compensatory damages in an amount to be proven at trial and in excess of $50,000 and this Court's arbitrational limit;

b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of Penn Medicine's conduct;

c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

d. For punitive damages in excess of $50,000 and this Court's arbitrational limit resulting from Penn Medicine and Pennsylvania Hospital's oppressive, reckless, and/or malicious conduct, as permitted by law;

e. For interest as permitted by law;

f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and

g. For such other and further relief as the Court deems proper.

COUNT VII: CORPORATE LIABILITY OF HEALTH-CARE PROVIDER
(Against Penn Medicine and Pennsylvania Hospital)

126. Plaintiff incorporates by references each of the preceding paragraphs as if fully set forth herein.

127. At all relevant times, Penn Medicine and Pennsylvania Hospital owed a duty of care to the Injured Infant to ensure their safety and well-being while the Injured Infant was under the care of Pennsylvania Hospital staff. Specifically, Penn Medicine and Pennsylvania Hospital had a duty to the Injured Infant to formulate, adopt, and enforce adequate rules and policies to ensure quality care for the Injured Infant. Further, Penn Medicine and Pennsylvania Hospital owed a duty to the Injured Infant to oversee its healthcare professionals and medical staff that provided patient care to the Injured Infant.

128. Penn Medicine and Pennsylvania Hospital owed a duty to its patients, and the Injured Infant in particular, to formulate, adopt, and enforce adequate rules and policies for the purchase, supply, distribution, and use of products that were free of unreasonable risk of harm when used in their intended manner and for their intended purpose and ensured quality care for the Injured Infant.

129. At all times relevant to this action, the Injured Infant used the cow's milk-based products purchased, supplied, and/or distributed by Penn Medicine and Pennsylvania Hospital in their intended manner and for their intended purpose.

130. Moreover, at all relevant times, Penn Medicine and Pennsylvania Hospital knowingly authorized the Defendant Manufacturers' sales representatives to market, advertise, distribute,

and/or sell their products at Pennsylvania Hospital. The Defendant Manufacturers' sales representatives were encouraged to interact with Pennsylvania Hospital's healthcare professionals and medical staff. These interactions provided the Defendant Manufacturers' sales representatives an opportunity to co-opt Pennsylvania Hospital's healthcare professionals and medical staff into assisting with the marketing, distribution, and/or sale of the Defendant Manufacturers' unreasonably dangerous products.

131. Penn Medicine and Pennsylvania Hospital also knowingly allowed the Defendant Manufacturers' sales representatives to routinely misrepresent the risks and benefits of Defendants' products to Pennsylvania Hospital's healthcare professionals and medical staff, including the misrepresentation that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants.

132. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known at the time that it formulated, adopted, and enforced its rules for the acquisition, distribution, and supply of the Defendant Manufacturers' cow's milk-based infant products, including the access afforded the Defendant Manufacturer's sales representatives, that these products significantly increased the risk of NEC, serious injury, and death for premature infants.

133. Penn Medicine and Pennsylvania Hospital knew or reasonably should have known that its medical professionals and the parents of premature infants, including the Plaintiff Parent, would not have realized the risks associated with feeding cow's milk-based formula to premature infants.

134. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, recklessly and breached its duty by:

a. Failing to formulate, adopt, and enforce adequate rules and policies that would have restricted the use of cow's milk-based products for feeding premature babies; and/or

b. Failing to formulate, adopt, and enforce adequate rules and policies that warned the Plaintiff Parent that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in premature babies, like the Injured Infant; and/or

c. Failing to formulate, adopt, and enforce adequate rules and policies that warned its healthcare professionals and medical staff that cow's milk-based products are unsafe and/or contraindicated for premature babies like the Injured Infant; and/or

d. Failing to formulate, adopt, and enforce adequate rules and policies to instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or

e. Failing to formulate, adopt, and enforce adequate rules and policies to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or

f. Failing to formulate, adopt, and enforce adequate rules and policies to ensure a warning in a method reasonably calculated/expected to reach the parents of newborns, like the Plaintiff Parent; and/or

g. Failing to formulate, adopt, and enforce adequate rules and policies to prevent the Defendant Manufacturers' sales representative from misrepresenting to

Pennsylvania Hospital's healthcare professionals and medical staff that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants; and/or

h. Failing to establish a donor milk program that was sufficient to meet the needs of the premature babies, like the Injured Infant.

135. A reasonable hospital under the same or similar circumstances would have formulated, adopted, and enforced adequate policies, and rules to restrict the feeding of cow's milk-based products to premature babies, including developing an adequate donor milk program, instructing its healthcare professionals and medical staff on the safe use of Defendants Manufacturers' cow's milk-based products, and restricting the marketing of the Defendant Manufacturers' unreasonably dangerous products to its healthcare professionals, medical staff, and parents of premature infants under its care.

136. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to formulate, adopt, and enforce adequate rules and policies to ensure the quality care of its patients, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

137. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital failure to formulate and enforce adequate policies and rules related to the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

138. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital negligent and reckless conduct the Plaintiff Parent suffered significant emotional distress, loss of

income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

139. In the alternative, Penn Medicine and Pennsylvania Hospital owed a duty to its patients, and the Injured Infant in particular, to oversee the practicing healthcare professionals and medical staff that provided the products at issue to infants under Pennsylvania Hospital's care, including the Injured Infant.

140. Penn Medicine and Pennsylvania Hospital employed or contracted with the healthcare professionals and medical staff at Pennsylvania Hospital and was responsible for overseeing those individuals during their treatment of the Injured Infant.

141. Nonetheless, Penn Medicine and Pennsylvania Hospital acted negligently, recklessly and breached its duty by:

a. Failing to oversee its healthcare professionals and medical staff on their use of cow's milk-based products for feeding premature babies; and/or

b. Failing to warn or instruct its healthcare professionals and medical staff that cow's milk-based products significantly increase the risk of NEC, severe injury, and death in those babies; and/or

c. Failing to warn or instruct its healthcare professionals and medical staff that cow's milk-based products are unsafe and/or contraindicated for premature babies like the Injured Infant; and/or

d. Failing to oversee its healthcare professionals and medical staff to restrict their feeding of cow's milk-based products to premature babies; and/or

e. Failing to warn or instruct its healthcare professionals and medical staff on the information that should be provided to parents in order to make an informed choice

about whether to allow their babies to be fed the Defendant Manufacturers' products, notwithstanding their substantial risk; and/or

f. Failing to provide its healthcare professionals and medical staff with the well-researched and well-established studies that link cow's milk-based products to NEC and death in premature infants; and/or

g. Failing to provide its healthcare professionals and medical staff with warnings about the dangers of the Defendants' Manufacturers products in a method reasonably calculated/expected to reach the parents of newborns; and/or

h. Failing to provide statistical evidence to its healthcare professionals and medical staff showing the magnitude of increased risk of NEC in premature infants associated with cow's milk-based products; and/or

i. Failing to oversee its healthcare professionals and medical staff to ensure that the Defendant Manufacturers' sales representatives' misrepresentations that premature babies would not grow adequately with human milk and human milk products and that use of donor milk was not advised for premature infants had not influenced the use and/or misuse of the Defendant Manufacturers' products.

142. A reasonable hospital under the same or similar circumstances would have warned of the above risks, would have instructed its healthcare professionals and medical staff on the safe use of the Defendant Manufacturers' products, and would have restricted the ability of the Defendant Manufacturers' sales representatives to market the Defendant Manufacturers' unreasonably dangerous products without adequate warning.

143. A reasonable hospital under the same or similar circumstances would have overseen and managed its healthcare professionals and medical staff to ensure that they received proper training and updating on the risks associated with feeding cow's milk-based formula to premature infants.

144. Had Penn Medicine and Pennsylvania Hospital exercised reasonable care by satisfying its duty to oversee its healthcare professionals and medical staff who provide patient care, the Injured Infant would not have been exposed to the Defendant Manufacturers' cow's milk-based products.

145. As a direct and proximate result of Penn Medicine and Pennsylvania Hospital's failure to oversee its healthcare professionals and medical staff on the danger posed by the Defendant Manufacturers' unreasonably dangerous cow's milk-based products, the Injured Infant was fed the Defendant Manufacturers' cow's milk-based products, which caused and/or increased the risk of developing NEC and significant injuries.

146. As a further direct and proximate result of Penn Medicine and Pennsylvania Hospital's negligent and reckless conduct, , the Plaintiff Parent suffered significant emotional distress, loss of income, and/or other harms. Her life has been significantly affected by the Injured Infant's injuries.

WHEREFORE, Plaintiff demands judgment against Penn Medicine and Pennsylvania Hospital as follows:

a. For compensatory damages in an amount to be proven at trial and in excess of $50,000 and this Court's arbitrational limit;

b. For damages for past, present, and future emotional distress, loss of enjoyment of life, pain and suffering, mental anguish, and other non-economic losses sustained as a result of Penn Medicine and Pennsylvania Hospital's conduct;

c. For past, present, and future out-of-pocket costs, lost income and/or lost revenue, and/or lost profits, and/or lost business opportunity, lost earning capacity, and costs related to medical or mental health treatment which have or may be recommended;

d. For punitive damages in excess of $50,000 and this Court's arbitrational limit resulting from Penn Medicine's oppressive, fraudulent, and/or malicious conduct, as permitted by law;

e. For interest as permitted by law;

f. For attorney's fees, expenses, and recoverable costs incurred in connection with this action; and

g. For such other and further relief as the Court deems proper.

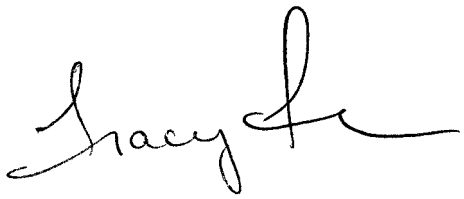
DEMAND FOR JURY TRIAL

147. Plaintiff hereby demands a jury trial for all claims triable.

Dated: March 24, 2022

Respectfully submitted,

ANAPOL WEISS



Tracy Finken
130 N. 18th Street, Suite 1600
Philadelphia, PA 19103
Phone: (215) 735-1130
Email: tfinken@anapolweiss.com

KELLER LENKNER LLC
Ashley Keller (*pro hac vice forthcoming*)
150 N. Riverside Plaza, Suite 4100
Chicago, Illinois 60606
Telephone: (312) 741-5220

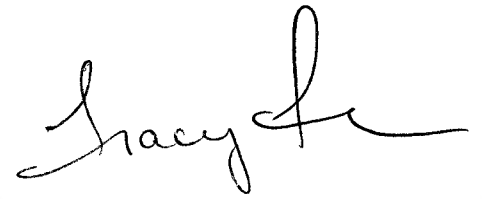
Fax: (312) 971-3502
Email: ack@kellerlenkner.com

WALSH LAW PLLC
Alex Walsh (*pro hac vice forthcoming*)
1050 Connecticut Ave, NW, Suite 500
Washington, D.C. 20036
Telephone: (202) 780-4127
Fax: (202) 780-3678
Email: awalsh@alexwalshlaw.com

Attorneys for Plaintiff

CERTIFICATE OF SERVICE

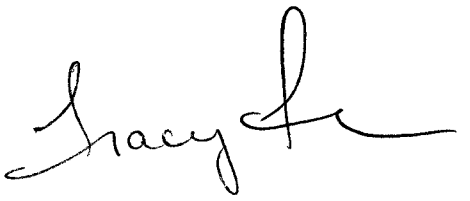
I hereby certify that on March 24, 2022, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF and that the foregoing document is being served on all counsel of record or parties registered to receive CM/ECF Electronic Filings.



Tracy Finken

VERIFICATION

I, the undersigned, Tracy Finken, verify that the statements made in this document are true and correct to the best of my knowledge, information, and belief. I understand that false statements herein are made subject to the penalties of 18 Pa. C.S. §4904, relating to unsworn falsification to authorities.



Date: March 24, 2022

Tracy Finken